Information on Applying for Medical Device Clinical Trials

2022.5.1

I. Clinical Trial Application Procedure:

To apply for a medical device clinical trial, the following materials in quintuplicate (including the hard copy and the optical disc, one original copy and two duplicate copies of each) shall be submitted to the Food and Drug Administration of the Ministry of Health and Welfare (the TFDA):

□ 1. Application Form for Medical Device Clinical Trials (Appendix 1)

*□2. A photocopy of Medical device business permit

□ 3. If a Clinical Trial Institutional Review Board approval letter, foreign marketing authorization, or Certificate of Approval for Clinical Trials issued by a foreign competent health authority or an Institutional Review Board is available, enclose such document(s).

□ 4. Chinese Synopsis for the Clinical investigation plan (Appendix 2)

□ 5. Clinical investigation plan (refer to Appendix 3), with version and date indicated; signatures of the sponsor and of the Principal Investigator are required.

□ 6. Informed Consent Form (refer to Appendix 4), with version and date indicated; Principal Investigator's signature is required.

*□ 7. Case Report Form (refer to Appendix 5)

□ 8. Certification that the Principal Investigator is in compliance with the education, experience, and number of hours of relevant training completed stipulated by Regulations on

Good Clinical Practice for Medical Devices (Principal Investigator's signature is required)

*□ 9. Evaluation report produced by clinical trial institution for the proper conduct of the clinical trial

□ 10. Information and related documents for compensation available in the event of injury and loss arising from participation in the clinical trial (e.g., written confirmation of insurance coverage)

*□ 11. Investigator’s Brochure (refer to Appendix 6)

□ 12. Preclinical information and instructions of the investigational medical device (refer to Appendix 7)

*□ 13. Review fee for reviewing the clinical trial protocol (handle in accordance with Standards of Administrative Fees for Medical Devices)

II. Expedited Procedure:

For medical device clinical trials approved to be conducted by the US Food and Drug Administration (FDA), in addition to enclosing the relevant materials when applying for a clinical trial (one hard copy and one optical disc), the following supporting documents may be enclosed; once approved by the TFDA, the expedited procedure will be carried out. In the event of any amendment to the clinical trial protocol, the applicant shall still enclose relevant data that has been amend , as well as the following supporting documents. The trial may only be conducted upon approval by the TFDA.

□ 1. Affidavit (Appendix 8), with affixture of the official seal and the seal of the person in charge to indicate responsibility

□ 2. U.S. FDA's official letter approving conduct of the clinical

trial

□ 3. Letter of Approval from the Institutional Review Board of U.S. clinical trial institution

III. Clinical Trial Amendment:

When there are changes to the Protocol or Protocol Addendum, the Informed Consent Form, the clinical trial institution, the Principal Investigator, the sponsor, or the product name, manufacturer, specifications, or manufacturing process of the investigational medical device, one copy of each of the following materials (including both hard copy and optical disc) shall be submitted:

- □ 1. Application Form for Medical Device Clinical Trials (Appendix 1)
- □ 2. Copies of previous official documents verifying approval from the Ministry of Health and Welfare
- □ 3. Documents and information from before and after the amendment
- □ 4. A list of changes in the clinical investigation plan to compare the content before and after the amendment
- □ 5. Review fee for reviewing the medical device clinical trial amendment (handle in accordance with Standards of Administrative Fees for Medical Devices)

IV. Status reports of clinical trial:

During the term of clinical trial conduction, one copy of each of the following materials (including both hard copy and optical disc) shall be submitted to TFDA in accordance with the official document certifying the approval of the clinical trial:

□ 1. Application Form for Medical Device Clinical Trials (Appendix 1)

□ 2. Copies of previous official documents verifying approval from the Ministry of Health and Welfare

□ 3. Interim Report (refer to Appendix 9); Principal Investigator's signature is required.

V. Filing Clinical Investigation Report for Reference:

To file clinical investigation report for reference for a medical device clinical trial, one copy of each of the following materials (including hard copy and optical disc) shall be submitted:

□ 1. Application Form for Medical Device Clinical Trials (Appendix 1)

□ 2. Copies of previous official documents verifying approval from the Ministry of Health and Welfare (including special approval for investigational medical devices)

□ 3. Clinical Investigation Report (refer to Appendix 10); signatures of the sponsor and of the Principal Investigator are required.

□ 4. Overview of study site enrollment (refer to Appendix 11)

*□ 5. Review fee for reviewing the medical device clinical trial report (handle in accordance with Standards of Administrative Fees for Medical Devices)

VI. Investigational Medical Device:

For medical device clinical trials approved by the TFDA， medical device firm , pharmaceutical firm, or clinical trial institution may apply for special approval to import investigational medical devices in accordance with Regulations for Special Approval of Manufacturing or Importing Specific Medical Devices.

Note:

1. If the clinical trial is initiated by clinical trial institution ; documents marked with “*” may be waived.
2. The materials stored on the optical disc should be consistent with the hard copy and should be written in retrievable information such as word, odt, or pdf.
3.The TFDA may require the submission of other relevant materials if such is considered necessary.

Appendix 1

Application Form for Medical Device Clinical Trials

2022.5.1

1. ☐ For registration 2. ☐ Expedited ☐ Re-examination 3. ☐ New application ☐ Amendment

☐Status reports of clinical trial

☐ Filing Clinical Investigation report for Reference

1. ☐ Academic research 2. ☐ Expedited ☐ Re-examination 3. ☐ New application

☐ Amendment

☐ Status reports of clinical trial

☐ Filing Clinical Investigation report for Reference

★ Please check sequentially *1—3* (to facilitate expediting of the process)

Recipient	Food and Drug Administration, Ministry of Health and Welfare
Case number (* See Instructions for Completing Form)	
The title of the clinical trial	
Investigational Medical device name	
Review fees	NT$_____exactly

Applicant	Name of firm/hospital: Seal

	Person in charge: Seal Address: (If the applicant is a hospital, an official letter may be issued to replace this field.)
Contact person	Name: Telephone: e-mail: Year Month Day
Remarks	

* Instructions for Completing Form:

There is no need to complete this form for new cases. For Re-examination , please provide the original application case number. For amendments, status reports of clinical trial , or to file clinical investigation report for reference, please provide the original approval document number.

Appendix 2

Chinese Synopsis for the Medical Device Clinical Trial Protocol

2022.5.1

I. The number of the clinical trial :

II. The title of the clinical trial:

Chinese title:

English title: (if necessary)

III. The name of sponsor:

IV. Clinical trial institution and Principal Investigator:

1. The name of the clinical trial institution :
2. The name and title of the principal Investigator:

V. Investigational medical device:

1. Product name:
2. Model /Type:
3. Name of manufacturer:
4. Address of manufacturer:
5. Indications/intended use:
6. Classification (if known):
7. Marketing status:
   - □ Marketed domestically (Certificate No._____)
   - □ Yet to be marketed domestically
   - □ Marketed in other countries (countries:)
   - □ Yet to be marketed in other countries

VI. Purpose of Clinical trial:

VII. Clinical trial design:

1. ☐ Controlled (☐Comparator medical device ☐ Other___)
   □ Non-controlled
2. ☐ Open-label ☐ Evaluator-blinded
   □ Single-blind ☐ Double-blind
   □ Other_____
3. ☐ Randomized ☐ Non-randomized
4. ☐ Parallel-group ☐ Cross-over

☐ Other_____

5. ☐ International multicenter ☐ Taiwan multicenter
   ☐ Taiwan single-center
6. Expected duration of trial: __Year __Month ~ __Year___Month

VIII. Outcome Measures :

1. Primary Outcome Measures:

2. Secondary Outcome Measures:

IX. Inclusion and exclusion criteria:

1. Inclusion criteria:

2. Exclusion criteria:

X. Study Procedure: (If process flowchart or schedule is available, enclose such.)

XI. Concomitant medical dispositions:

1. Allowed concomitant medical dispositions:

2. Prohibited concomitant medical dispositions:

XII. Statistics:

1. Primary study hypothesis: ☐ Superiority study ☐ Non-inferiority study ☐ Equivalence study ☐ Other_____
2. Sample size: Number of participants enrolled____Number of valid subjects _____
   Total number of subjects in Taiwan _____
   Total number of subjects worldwide_____
3. Efficacy assessment population: ☐ Intent to treat (ITT) ☐ Per-protocol (PP) ☐ Other_____
4. Safety assessment population: ☐ Intent to treat (ITT) ☐ Per-protocol (PP) ☐ Other_____
5. Statistical methods for efficacy/safety assessment indicators:

6. Status reports of clinical trial : ☐ Yes ☐ No

Appendix 3

Important Items to be Included in the Medical Device Clinical Investigation Plan

2022.5.1

1. General Information	
1.1	The title of the clinical trial
1.2	The number of the clinical trial
1.3	Version number and development date of the clinical investigation plan
1.4	Summary of revision history
1.5	Name and address of sponsor
1.6	Name and title of the Principal Investigator and Sub-investigator(s)
1.7	Name and address of clinical trial institution
1.8	Names and addresses of other institutions participating in the clinical trial
1.9	Abstract or summary of the clinical trial, which must include relevant information on clinical trial design, e.g., inclusion and exclusion criteria, number of subjects, duration of clinical trial, follow-up period, clinical trial purpose, and outcome measure
2. Identification and description of the investigational medical device	
2.1	Summary of the investigational medical device and intended use
2.2	Information for the investigational medical device's manufacturer
2.3	Name or number of the specification/model number, including version of the software and its accessories
2.4	Traceability of the investigational medical device, e.g., batch number, lot number, or serial number
2.5	Intended use of the investigational medical device in the clinical trial
2.6	Intended use population and indications of the investigational medical device
2.7	Materials in the investigational medical device that will come in contact with human tissues or body fluids
2.8	Required training and experience for users of the investigational medical device
2.9	Relevant medical or surgical procedures for the investigational medical device
3. Theoretical basis and clinical trial design rationale	
3.1	The rationale for using the investigational medical device in humans shall be evaluated in accordance with preclinical test results.
3.2	The rationale for the clinical trial design shall be evaluated using relevant clinical data for the current clinical trial
4. Risks and benefits of the investigational medical device and of the clinical trial	
4.1	Anticipated clinical benefits
4.2	Anticipated adverse device effect
4.3	Residual risks identified in the risk analysis report for the investigational medical device
4.4	Risks associated with participation in the clinical trial
4.5	Possible interactions with concomitant medical dispositions
4.6	Measures that will be taken to control or mitigate the risks
4.7	Assessment regarding reasonableness of risks versus benefits

5. Purpose and Hypothesis of the Clinical Trial	
5.1	Primary and secondary purposes
5.2	Primary and secondary hypothesis , which are determined to be accepted or rejected in accordance with the statistical data of the clinical trial
5.3	Claimed and expected effectiveness of the investigational medical device to be qualified
5.4	Risks to be evaluated and anticipated adverse device effect
6. Clinical trial Design	
6.1	Type of clinical trial design (e.g., double-blind, parallel-design, controlled or not) and explanation of why such was chosen
6.2	Methods to reduce or avoid deviations, e.g., randomization and blinding/masking
6.3	Primary and secondary outcome measures and explanation of why such was chosen
6.4	Methods and timing for assessing, recording, and analyzing parameters
6.5	Equipment required for evaluating parameters, as well as equipment maintenance and calibration arrangements
6.6	Processes for employing the investigational medical device and the control group
6.7	Rationale for the choice in control group
6.8	List of other medical devices or medicinal products used in the clinical trial
6.9	Required number of investigational medical devices and explanation of rationale thereof
6.10	Subject inclusion criteria
6.11	Subject exclusion criteria
6.12	Criteria and procedures for subjects to withdraw or discontinue
6.13	Timing of enrolment
6.14	Duration of subject participation in the clinical trial
6.15	Expected number of subjects to be enrolled
6.16	Time needed to enroll expected number of subjects
6.17	All study procedures that subjects will undergo throughout the clinical trial
6.18	The follow-up period shall be sufficient to demonstrate the effectiveness of the investigational medical device, and sufficient to evaluate adverse device effect
6.19	Medical care provided to subjects after the clinical trial is completed
6.20	Known or foreseeable factors that are likely to affect clinical trial results
6.21	Summary of the monitoring plan, which shall include access to source data and the extent of source data verification planned
7. Statistical Considerations	
7.1	Statistical design, method, and analytical procedures
7.2	Sample size
7.3	the level of significance and the power
7.4	Expected withdraw rate
7.5	Criteria for determining success or failure of clinical trial results
7.6	Interim analysis
7.7	Criteria for terminating the clinical trial from a statistical perspective

7.8	Procedure for reporting deviations from the original statistical plan
7.9	The specification of subgroups for analysis
7.10	All procedures for including data in the analysis
7.11	The treatment of missing, unused or spurious data, including withdrawals
7.12	Specific data excluded from hypothesis testing
7.13	In a multicenter clinical trial, the maximum and minimum number of subjects enrolled at respective clinical trial institutions
8. Data management	
8.1	Procedures for reviewing data, for database organization, and for addressing issues associated with data
8.2	Procedures for verification, validation and securing of electronic data processing systems
8.3	Procedures for and durations of data protection
8.4	Other quality assurance procedures
9. Amendments to the clinical investigation plan	
9	Description of the procedures to amend the clinical investigation plan.
10. Deviations from the Clinical Trial Protocol	
10.1	Statement that it is disallowed for the Principal Investigator to deviate from the clinical investigation plan, except in special circumstances specified in the plan
10.2	Procedures for recording, reporting, and analyzing deviations from the Clinical investigation plan
10.3	Reporting requirements and deadlines
10.4	Corrective and preventive measures, and criteria for removal of Principal Investigator status
11. Investigational medical device accountability	
11	Procedures for the accountability of investigational medical devices used in the trial
12. Statements of Compliance	
12.1	Declaration that the ethical principles of the Declaration of Helsinki are followed
12.2	Declaration that the Regulations on Good Clinical Practice for Medical Devices and the applicable domestic laws and regulations are followed
12.3	Declaration that the clinical trial will only be conducted following approval by the competent authority and the IRB
12.4	Declaration that the stipulations of the competent authority and those of the IRB are followed
12.5	Statement regarding types of insurance available for subjects
13. Informed Consent Process	
13.1	General process to obtain informed consent, including that for providing subjects with new information
13.2	Informed consent process for situations where subjects cannot exercise consent on their own or in emergencies
14. Adverse Events, adverse device effect, and Deficiencies Associated with Medical Devices	
14.1	Definitions of adverse event and adverse device effect

14.2	Definition of medical device deficiency.
14.3	Definition of serious adverse event and serious adverse device effect to medical device; definition of unexpected serious adverse device effect to medical device
14.4	Deadline for the Principal Investigator to report all adverse events and deficiencies associated with medical devices to the sponsor
14.5	Procedure for reporting adverse events (e.g., date, treatment or disposition, evaluation of severity, assessment regarding correlation with the medical device used in the trial)
14.6	Procedures for reporting deficiencies associated with medical device
14.7	Anticipated adverse events and adverse device effect , as well as descriptions of incidence, treatment, or disposition thereof
14.8	Procedures for reporting serious adverse events and serious adverse device effect
14.9	Information regarding the Data Monitoring Board
15. Vulnerable Populations	
15	If the subjects belong to a vulnerable population, the informed consent process and medical care available to subjects after completion of the clinical trial shall be explained.
16. Suspension or Premature Termination of Clinical Trial	
16.1	The criteria for the whole clinical trial or certain clinical trial institutions to be discontinued or terminated early, as well as subsequent arrangements for such
16.2	The criteria for unblinding upon suspension or premature termination of the clinical trial
16.3	Requirements for subject follow-up
17. Publication Strategy	
17	Statement regarding whether or not clinical trial results will be released, and criteria for releasing them
18. References	
18	List of relevant references for the clinical trial

Appendix 4

Medical Device Clinical Trial Informed Consent Form Template

2022.5.1

The title of the clinical trial : Chinese title: English title: (if necessary)
Clinical trial institution: Sponsor: Principal Investigator: Title: Telephone: Sub-investigator: Title: Telephone: ※ 24-hour emergency contact person: Telephone:
Full name of subject: Sex: Gender: Medical record no.:

You are being invited to participate in this clinical trial. The form will provide information related to this trial. The principal investigator or his/her authorized staff will explain the content of this trial to you and respond to your questions. Please do not sign this consent form until you are satisfied with all the answers to your questions. You do not have to decide immediately whether to participate in the clinical trial. It needs to be considered thoroughly before signing your name. You must sign the consent form to participate in this trial. If you are willing to participate in this trial, this document will be considered as the record of your consent. You can withdraw from the trial without any reason, even after you have given consent.

I. Current information about the investigational medical device: 1. General information of the investigational medical device: 2. Current global marketing status of investigational medical device: (It shall be stated that the medical device used in this trial has not been approved by the Ministry of Health and Welfare for marketing, or that it has been approved by the Ministry of Health and Welfare for marketing yet the indication under investigation is beyond the scope approved.)
II. Purpose of the clinical trial:

III. Main inclusion and exclusion criteria for the clinical trial:

1. Inclusion criteria:
2. Exclusion criteria:

(It should be written to be understood easily by the subject.)

IV. Methods and Relevant Test of this trial:
V. Possible risks and their incidence and countermeasures: 1. Risks associated with the investigational device (side effects and adverse device effect of the device used in this trial) 2. Risks associated with the trial process
VI. Other possible therapeutic methods and explanations:
VII. Expected trial benefits:
VIII. Contraindications, restrictions, and requirements for subjects during the trial:
IX. Confidentiality of subject's personal information:
X. Withdrawal and suspension of the trial: You are free to decide whether to take part in this trial. During the trial, you can withdraw your consent and leave the trial at any time, without giving any reason, and no unpleasantness will be caused, nor will your medical care from your physician be affected. It is also possible that the Principal Investigator or the Trial Sponsor will suspend the clinical trial whenever necessary.

XI Medical care, Compensation and Insurance:

1. If you experience damages due to adverse effects that occur as a result of participating in this clinical trial,_____Company (or jointly with _____ Hospital) will be responsible for compensation (refer to the appendix for information on indemnification, such as the insurance policy and/or the hospital's compensation guidelines). However, no compensation is available for damages resulting from expected adverse effects, as documented in this Informed Consent Form.
2. The hospital will provide you with professional medical care and consultation in the event that you have adverse effects or damages that occur as a result of your participation in this clinical trial. You do not need to bear necessary medical expenses for treating adverse effects or damages.
3. With the exception of the compensation and medical care mentioned in the foregoing two paragraphs, this trial provides no other forms of compensation. If you are unwilling to take such risks, do not take part in the trial.
4. By signing this Informed Consent form, you will not lose any of the legal rights you are entitled to.
5. This study is ☐ covered by liability insurance ☐ not covered by liability insurance. (Note: It is up to the sponsor and the clinical trial institution whether or not to include insurance information.)

XII. Storage, use and reuse of subject's samples (including their derivatives) and personal information

1. Storage and use of samples (including their derivatives):
2. Storage and reuse of residual samples:

XIII Subject Rights:

1. No fees related to this trial will be collected from you, and this trial is not covered by National Health Insurance.
2. During the trial, any new information or major finding concerning your health or disease that may affect your willingness to continue with the clinical trial will be provided to you in a timely manner.
3. During the trial, if you have any questions about the nature of the trial or any concerns about your rights as a subject, or suspect that you have suffered injury as a result of participating in this trial, please contact the (name of hospital IRB) to request for consultation. The telephone number is .
4. To facilitate conduct of the trial, you must receive care from Dr. . If you have any questions or situations now or throughout the trial, please do not hesitate to contact Dr.____at the Division of__ Department of the hospital (_____**24**-hour contact phone number:_____).
5. This consent form is prepared in _____. The physician has given you a copy of the signed consent form and has fully explained the nature and purpose of the trial. The physician has answered all your questions about the investigational medical device and the trial procedure.

XIV.Signature:

Appendix 5

Important Items to Be Included in the Case Report Form

2022.5.1

1. Cover Page/Log-in Page	
1.1	Name or logo of sponsor
1.2	Version and date of clinical investigation plan
1.3	Version number of Case Report Form
1.4	Title or number of clinical investigation plan
2. Header or Footer/Identifier of Electronic Case Report Form	
2.1	Title or number of clinical investigation plan
2.2	Version number of Case Report Form
2.3	Identifier for clinical trial institution/Principal Investigator
2.4	Subject code and other identification, e.g., date of birth
2.5	Case Report Form number, date of visit, or number
2.6	Page number and total number of pages
3. Items to Be Included in Case Report Form	
3.1	Screening
3.2	Subject informed consent records
3.3	Inclusion/exclusion
3.4	Baseline visit: Demographics of the subject, diagnosis, prior medications,device or medical dispositions, date of inclusion in this trial
3.5	Interventional treatment
3.6	Follow-up visit
3.7	Clinical trial procedures
3.8	Adverse events
3.9	Deficiencies associated with medical devices
3.10	Concomitant illnesses/concomitant medications or device
3.11	Unscheduled visits
3.12	Subject diary
3.13	Subject withdrawal or lost to follow-up
3.14	Signature of the Principal Investigator or his/her authorizer on records regarding completion of clinical trial
3.15	Deviations from clinical investigation plan

Appendix 6

Important Items to be Included in the Investigator's Brochure

2022.5.1

1. General Information	
1.1	Product name of the investigational medical device
1.2	Number of the Investigator's Brochure
1.3	Version and date of the Investigator's Brochure
1.4	Confidentiality Statement
1.5	Summary of revision history
1.6	Page number and total number of pages
1.7	Name and address of the sponsor or manufacturer of the investigational medical device
2. Investigational Medical Device Information	
2.1	Summary of publications supporting the rationale for the clinical trial design and intended use of the investigational medical device
2.2	Classification of investigational medical device
2.3	Investigational medical device components and materials
2.4	Summary of the manufacturing process flow and of the validation procedure for the investigational medical device
2.5	Investigational medical device working principles and supporting scientific publications
2.6	Instructions for installation and use of the investigational medical device, including storage and operating conditions, preparations prior to use or repeated use, confirmation regarding safety or efficacy prior to use, and precautions after use
2.7	Expected efficacy of the investigational medical device
3. Preclinical Testing	
3.1	Design calculations
3.2	In-vitro tests
3.3	Mechanical and electrical tests
3.4	Reliability tests
3.5	Software validation regarding function of investigational medical device
3.6	Performance tests
3.7	Ex-vivo test
3.8	An evaluation of biological safety
4. Clinical Data	
4.1	Summary of prior uses in clinical settings of the investigational medical device and of products similar to it
4.2	Analysis of adverse device effect , and records regarding previous revisions or recalls of the investigational medical device
5. Risk Management	
5.1	Summary of risk analyses, including identification of residual risks

5.2	Result of the risk assessment
5.3	Anticipated risks, contraindications, and warnings for the investigational medical device
6. Regulations and References	
6	List of laws and regulations, international standards, and references followed

Appendix 7

Preclinical Data for Investigational Medical Device

2022.5.1

	Item	Standard
1.	Biocompatibility	ISO 10993 series
2.	Electrical safety	IEC 60601-1 series
3.	Electromagnetic compatibility	IEC 60601-1-2
4.	Sterilization validation	ISO 11135; ISO 11137 ISO 17665
5.	Software validation	IEC 62304
6.	Package, label, instructions	ISO 7000; ISO 15223
7.	Quality system	Medical Device Quality Management System Regulations ; ISO 13485
8.	Risk management	ISO 14971
9.	Particular requirements	ISO/TR 16142, product-relevant criteria

Appendix 8

Affidavit

This affidavit is signed concerning the matter of medical device clinical trial applied for by the institution with the Food and Drug Administration, Ministry of Health and Welfare, and the terms and conditions are hereinafter set forth:

I. The medical device clinical trial to be conducted in Taiwan:

The name of the investigational medical device	
The title of the clinical trial	
The number of the clinical trial	

The undersigned guarantees that the clinical trial number, contents, and relevant documents are completely identical to those approved by the U.S. Food and Drug Administration (FDA) (Approval No.:_____).

II. In the event that the clinical trial amendment is approved by or the clinical trial is terminated by the U.S. FDA, or the applicant applies for amendment or termination, the undersigned shall proactively notify the TFDA.

III. If untruthful information is provided or the agreement to which this affidavit pertains is violated, the undersigned takes full legal responsibility for such. In addition to cancellation of this application or other relevant applications by the TFDA, the undersigned (including the sponsor and the contract research organization) shall no longer be eligible to apply for this expedited procedure in the future, either.

IV. If the undersigned fails to conduct the clinical trial in compliance with the approved clinical trial protocol, or in the event of serious deviation, violation of medical ethics or violation of the Regulations on Good Clinical Practice for Medical Devices, all applications by the undersigned (including the sponsor and the contract research organization) shall be subject to general review procedures instead.

V. The undersigned agrees that the TFDA shall publish violations (including names of the institutions and their persons in charge) without objection.

Undersigned (Please affix the official seal and the seal of the person-in-charge)

Address of the Legal Representative

Year Month Day

Appendix 9

Status Report Template for Medical Device Clinical Trials

2022.5.1

Clinical trial number

Clinical trial title

Clinical trial institution

Number of subjects Expected:_____ Currently enrolled: _____

Serial no.	Subject code	Age	Group (not applicable if double-blind)	Date enrolled	Date of investigational medical device use	Status***1**	Date withdrawn/completed	Reason for withdrawal	Serious adverse event (SAE) Category***2**	Date of occurrence(s)	Date reported to the competent authority	Relationship with the investigational medical device (as determined by the Principal Investigator) ***3**	Current status of subject
1													
2													
3													
4													
5													

***1** Status: A Screen failure B Screening C Ongoing D Early withdrawal E Completed

***2** Category: A Death B Life-threatening condition C Temporary or permanent disability D Congenital anomaly of fetus or infant of the subject E Requiring hospitalization or prolonged hospitalization F Other complications that may result in permanent injuries

***3** Relationship with the investigational medical device: A Definitely relevant B Probably relevant C Possibly relevant D Unlikely relevant E UnrelatedF Unassessable

Signature of Principal Investigator:_____ Date:_____Year____Month___Day

Appendix 10

Important Items to be Included in the Medical Device Clinical Investigation Report

2022.5.1

1. Cover Page	
1.1	Clinical trial title
1.2	Identifying into for the investigational medical device, including product name and specification/model number
1.3	Brief descriptions of the clinical trial design, control group, duration of the trial, method of the trial, and subject population
1.4	Name and contact information for the sponsor or sponsor's representative
1.5	Identifying information for the clinical investigation plan
1.6	Name and employer of the Principal Investigator and other participants
1.7	Laws and regulations, international standards, or guidelines followed in this clinical trial
1.8	Report date
1.9	Report author
2. Table of Contents	
2.1	Page numbers of respective corresponding chapters and sections, including an overview of forms and figures
2.2	List of appendices
3. Summary	
3.1	Clinical trial title
3.2	Introduction
3.3	Clinical trial purpose
3.4	Subject population
3.5	Clinical trial method
3.6	Clinical trial results
3.7	Conclusion
3.8	Clinical trial start date
3.9	Trial completion date or early termination date
4. Introduction	
4.1	Brief descriptions of where the clinical trial is positioned in the research and development process for the investigational medical device
4.2	Guidelines followed during clinical investigation plan design
5. Investigational medical device	
5.1	Description of the investigational medical device
5.2	Intender use of the investigational medical device
5.3	Where there are previous intended use or indications for the investigational medical device, specify such.
5.4	Amendments made to the investigational medical device or the Investigator's Brochure during the trial, including materials, software, device composition,

	shelf life, storage conditions, and instructions for use
6. Clinical investigation plan synopsis	
6.1	Clinical trial purpose
6.2	Clinical trial design, including the type and outcome measure
6.3	Ethical concerns
6.4	Data quality assurance
6.5	Subject population, including inclusion and exclusion criteria and sample size
6.6	Trial schedule
6.7	Concomitant medications/medical device/medical dispositions
6.8	Follow-up period
6.9	Statistical analysis, including clinical trial hypothesis, criteria for determining success or failure, sample size calculation, and statistical analysis methods
7. Results	
7.1	Clinical trial initiation date
7.2	Clinical trial completion/suspension date
7.3	The disposal of subjects and investigational medical devices
7.4	Subject demographics
7.5	Clinical investigation plan compliance
7.6	Efficacy analysis
7.7	Abstracts for all adverse events and adverse device effect, including severity, required treatment or disposition, and determination by the Principal Investigator regarding correlation with the investigational medical device or the trial procedure
7.8	Summary of all medical device deficiencies that are likely to result in serious adverse device effects and corrective actions adopted during the trial
7.9	Sub-group to be analyzed (e.g., by sex, gender, race, culture)
7.10	Management of missing values or deviations in data analysis, including subjects that have failed screening tests, are lost to follow-up or are withdrawn from the study, and reasons that they are withdrawn
8. Discussion and Conclusion	
8.1	Safety or performance results and any other outcome measure
8.2	Risk-benefit assessment
8.3	Discussion of clinical correlation and importance of trial results in accordance with other existing data
8.4	Specific interests or precautions concerning individual subjects or high-risk populations
8.5	Instructions regarding the need for further clinical trials in the future
8.6	Any limitation of the clinical trial
9. Abbreviations and Definitions	

9	List of abbreviations and definitions of terminology or rare terms
10. Ethics	
10.1	Confirmation of approval for both the clinical investigation plan and its amendments by the competent authority and the IRB
10.2	List of all IRBs (may be placed in appendix)
11. Clinical Trial Staff and Organizational Structure	
11.1	Brief description of the clinical trial organizational structure
11.2	List of those involved in the clinical trial, including their employers (may be placed in appendix)
11.3	Names and addresses of third-party institutions involved in the clinical trial (e.g., core laboratory, contract research organization, consultant, or other collaborators) (may be placed in appendix)
11.4	Name and address of sponsor or its representative
12. Signature Page	
12	The sponsor and all Principal Investigators shall sign the Clinical Investigation Report to indicate approval of its contents.
13. Appendix	
13.1	Study protocol, including amendments
13.2	Instructions for use of the investigational medical device
13.3	List of Principal Investigators and their clinical trial institutions, including summaries of their qualification and a copy of their CVs
13.4	List of the names and addresses of third parties involved in the clinical trial
13.5	List of monitors
13.6	List of IRBs
13.7	List of all important information, including deviations, adverse events, adverse device effect, deficiencies associated with medical devices, and subjects withdrawn from the study early
13.8	The audit certificate

Appendix 11

Overview of Enrollment at Clinical Trial Institutions

Clinical trial number						
Clinical trial title						
Sponsor						
Contract Research Organization						
Item / Clinical trial institution	Number of subjects screened	Number of subjects enrolled	Number of completed subjects	Number of early withdrawals	Number of AEs (x events/x persons)	Number of SAEs (x events/x persons)
1.						
2.						
3.						
4.						
5.						
Total						