Appendix 3

Medical Device Safety Summary Report

I. Medical device product information

(I) License number or listing number:

(II) Product name in Chinese:

(III) Product name in English:

(IV) Model number:

(V) Name of Manufacturer:

(VI) Country of Manufacturer:

(VII) License holder or firm that has completed the listing:

(VIII) Indications: (Shall be provided for indications that require surveillance)

II. Period of safety surveillance

Full surveillance period: ____Year(s)

Date of full surveillance: _____(MM/DD/YYYY) – _____(MM/DD/YYYY)

III. Status summary for the implementation of surveillance items

(Including but not limited to the quantity sold in the country, the summary of statistics and analyses of special situations such as serious and non-serious adverse event(s) occurred during the surveillance period, and the relevant reasons shall be evaluated.)

IV. Marketing status of the medical device in countries worldwide

(Including but not limited to the countries that sell the device and distribution of quantities sold, summary of the statistics and analyses of overseas serious and non-serious adverse event(s), etc.)

V. Actions taken by the local or foreign competent authority or medical device firm in response to medical device safety

(Including but not limited to the withdrawal from market or discontinuance of the medical device, license not renewed as scheduled, restriction of medical device sale, termination of clinical trial based on safety concerns, revision of use method, change of indications or applicable population, change of component parts, change of warnings or precautions in the instructions for use, release of safety notice or recall information, etc.)

VI. Changes of safety information in other countries

(Including but not limited to the changes of information related to medical device safety in the instructions of use (except for the warnings or precautions), related information on the occurrence of medical device adverse events or known side effects that have a significantly increased trend in frequency or severity, etc.)

VII. Clinical trial

(Including the medical device postmarket and safety related clinical research or analysis results, and literature publication of clinical research on safety. If there is no relevant literature, please provide the date of literature search, the searched database, and the query conditions.)

VIII. Risk management plan and benefits-risk analysis results

(Including hazards not identified before, hazards exceeding acceptable risks, risk reassessment, and analysis of medical benefits and overall residual risks)

IX. Overall safety evaluation

X. Summary

XI. Exhibit/Appendix

(I) Summary table (Additional explanation is required if the period of time of the data collected overseas for statistics is different from the start and end date of the local surveillance period. Non-serious adverse events shall include customer complaints.)

	Local					
Surveillance Period	Quantity sold	Estimated number of users	Serious adverse event(s)	Non-serious adverse event(s)	Number of journal articles	Number of cases published
Appendix index number						
	Overseas					
Surveillance Period	Quantity sold	Estimated number of users	Serious adverse event(s)	Non-serious adverse event(s)	Number of journal articles	Number of cases published
Appendix index number						

(II) Data of local sales distribution (Please specify if the device is rented.)

Level of medical institutions	Quantity sold	Estimated number of users (or times)
Medical centers		
Regional hospitals		
Local hospitals		
Clinics		
Others		