Questions and Answers for Post-market Application of Changes to an Existing Software as Medical Device

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I. Introduction

The Taiwan Food and Drug Administration, Ministry of Health and Welfare (hereinafter referred to as "TFDA") issued the "Questions and Answers for Post-market Application of Changes to an Existing Software as Medical Device" to assist companies with the understanding of the management of applications of changes in post-market medical device software in Taiwan. The Q&A will help companies manage the safety and effectiveness of post-market medical device software. Nonetheless, the Q&A does not cover and explain all medical device software products and hence the companies must evaluate if the changes in products affect the safety and effectiveness based on the architecture of the software and the technical properties of the design, and shall apply for changes of the licenses in compliance with the regulations. The medical device manufacturers could also send an inquiry letter which contains the medical device change information to the TFDA to check whether the changed products comply to the "Regulations Governing Issuance of Medical Device License, Listing and Annual Declaration" or not.

II. Questions and Answers

(1) How do the companies verify if the variations in medical device software are necessary to apply for change of license?

It is recommended to evaluate the change in the medical device software in advance. If the change of software, the cumulative effect of the upgrade, or the change in software, computer, hardware, and peripheral equipment do not affect the performance or purpose of the medical device software, and also do not affect the safety and effectiveness of use; or if the change does not belong to the provisions prescribed in Regulations Governing Issuance of Medical Device License, Listing and Annual Declaration as the items required for the change of license, it is not necessary to apply for the change of license. Nonetheless, the history of changes and relevant necessary measures from the course must be recorded and reserved.

If the matter of change belongs to the provision prescribed in Article 13 of Regulations Governing Issuance of Medical Device License, Listing and Annual Declaration, or affects the safety and effectiveness of medical

device software, change may only be made after approval of the central competent authority is obtained.

TFDA has issued the Guidance for Application for Changes in Post-Market Medical Device Software as a reference to help the companies understand the relevant management regulations for changes in post-market medical device software. Nonetheless, the Guidance does not cover and explain all products of medical device software. It is suggested to evaluate if the change of product affects the safety and effectiveness based on the technical properties of architecture and design of the software, and thereby apply for the change of license by law.

(2) Does the change in medical device firmware or mobile application (APP) require the application for the change of license ?

If the change in the medical device firmware or mobile application (App) affects the safety and effectiveness of the product (for example, the change related to revision of risk analysis), it is required to apply for the change of license pursuant to Regulations Governing Issuance of Medical Device License, Listing and Annual Declaration, to assure the safety and effectiveness of the products. Additionally, the Guidance for Application for Changes in Post-Market Medical Device Software issued by the TFDA may be used as reference. The applicable objects include the medical device software products with the license including but not limited to the firmware or mobile applications of the medical devices.

(3) Does the addition of network connection or change from the wired transmission to wireless transmission require the application for the change of license?

The addition of network connection or change from wired to the wireless transmission for medical devices is a change of specification, and this could affect the safety and effectiveness of products, such as cybersecurity. It is required to apply for the change of license pursuant to the Regulations Governing Issuance of Medical Device License, Listing and Annual Declaration.

(4) If input parameters or column remarks are added to the operating interface of products according to the user requirement, does it require the

application for the change of license?

It is recommended to verify in advance if the addition of new columns or parameters to the operating interface of the medical device software is the existing function of previously approved products. If not, it is necessary to evaluate if the addition of the medical device software can affect the safety and effectiveness. If the change certainly impact the safety and effectiveness, the manufacturers shall apply the change of license according to "Regulations Governing Issuance of Medical Device License, Listing and Annual Declaration".

(5) For the dataset of artificial intelligence medical devices using machine-learning technology featuring continuous changes, does it require the application for the change of license periodically?

The dataset for products of artificial intelligence/machine learning technology can be divided into training, validation, and testing dataset. If the change of training or validation dataset affects the safety and effectiveness of the products, it is required to apply for the change of license by regulations. For any concern, please make formal inquiry to TFDA.

(6) For product model using machine learning technology without affecting the product safety and effectiveness, is it allowed for the software to be debugged?

If the software debugging does not change the safety and effectiveness of the actual use from the previously approved product, and does not change the previously approved scope of the product (such as specification and efficacy), it is recognized as conforming to the quality control and maintenance of the products. This kind of debugging could waive the application of change. However, the manufacturer should still keep the revision history record properly.

(7) When the hardware or firmware working with the medical device software (such as Computed Tomography, Magnetic Resonance Imaging, and other instruments) has been changed, does the medical device software require the application for the change of license?

When the model, hardware or firmware of the medical device working with the medical device software changes, it is recommended to evaluate if such change affects the safety and effectiveness of the medical device software. For example, if the configuration and model training for the architecture of software devices were changed according to the data (such as medical imaging and data) from certain brands of medical devices, the change in the hardware or firmware for the instrument of a brand could likely affect the performance of the previously approved function of the product, and thus it is recommended to prepare the relevant supporting data and apply to TFDA for the change of license.

(8) Does the change of operating system of the medical device software require the application for the change of license ?

The upgrade (such as upgrading from Windows 7 to Windows 10) or change (such as changing from Windows to iOS) of the operating system version applicable to the medical device software could affect the system compatibility and function. To verify the consistency between the changed operating system and previous approval version, it is recommended to prepare the aforementioned supporting data to apply for the change. It shall be complied with the regulations governing the application for the change of license, in order to assure the product safety and effectiveness.

III. Reference

1. 2020.01.15, Medical Devices Act.
2. 2021.04.29, Regulations Governing Issuance of Medical Device License, Listing and Annual Declaration.
3. 2021.08.16, Guidance for Industry to Register Artificial Intelligence / Machine Learning - Based Software as Medical Device (AI/ML-Based SaMD).
4. 2021.12.30, Guidance for Application for Changes in Post-Market Medical Device Software.