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Guidance for Medical Software Classification

1. Introduction

Over the past few years, the information and communication technology advances rapidly and its innovations have been widely adopted by the medical device industry, particularly in the forms of software products ever present in medical care. A device classification system is the base of the medical device management; because of the broad applications of medical software a clear device classification is particularly crucial to its management. Hence in stipulation of this guidance document, the Taiwan Food and Drug Administration (FDA) referenced the regulation and management standards of other countries (such as the US, EU, Japan, etc.), while took into accounts the guidance articles of the International Medical Device Regulators Forum (IMDRF) to provide the industry sector a clear guidance in product development and registration, while to offer the user sector an insight into medical software management.

Due to ever-changing technological development, there is an unlimited supply of new products while differences are present between products of the same genre. As such the aim of this guidance is not to define all the medical software products. Instead, this guidance is to provide preliminary recommendations on device classification. If a product classification could not be determined accordingly, it is recommended to submit a classification request in accordance with Article 5 of Regulations Governing the Classification of Medical Devices.

This guidance was first published in 2015. With regards to the Medical Devices Act comes into force on May 1st 2021, and the development of clinical application and the international trend of medical devices management, some of the contents were modified in this version.

2. Scope

The term “Medical Software” mentioned in this guidance generally refers to the processing software in collection, storage, analysis, display, conversion of information regarding body conditions, vital signs and medical treatments. The device user entities include hospitals, residential users and long-range healthcare centers. In this guidance, the “Medical Software” administered under the Management of Medical Devices is referred to as a “Medical Device Software”.

3. Classification Principles of Medical Software

Not all medical software can be classified as medical devices. To determine if a software product is a medical device and hence should be administered accordingly, a comprehensive assessment of its functions, usages, operation methods, and working principles is required. The following principles could be beneficial to formulate the assessment:

(1) Does the product comply with the definitions of medical device in Article 3 of Medical Device Act?

(2) Does the product comply with the specifications listed in annex of Article 4 of Regulations Governing the Classification of Medical Devices

(3) Is the product claimed to have diagnostic or treatment functions or may assist in diagnosis or treatment?
(4) Importance of the product in disease treatment
(5) Contribution or reference value to disease diagnosis
(6) Potential hazards posed to human health

4. Possible Forms of Medical Device Software

(1) An Accessory of a Medical Device

Software built in or as an accessory of an electronic medical device, including the device operating or controlling software installed in computer interface, is an accessory of the device. Since delivery of the main body's (the host device) functions are dependent or influenced by the software, it is in general classified the same as its host device. If the software can expand or upgrade the functions of the host device beyond its original intended applications, then the software should be re-assessed for re-classification.

(2) Stand-alone Software

Stand-alone medical device software or an application is not a component of a medical device; in general it is placed onto the market alone without the devices. It is intended to be used for the purpose of process and analysis of information generated from the medical devices, assisting in diagnosis or treatment.

(3) Mobile Applications

Installed on mobile phones, tablets or other electronic devices, mobile applications may be used in conjunction with medical devices. If a mobile application is used for medical purposes, it should comply with the medical software regulations.

(4) Recording Media

Medical software that allows storage of information on physical storage medium, such as Compact Discs (CD), SD memory cards, and removable drives, or allows upload or download of information through internet servers, regardless of the supply method of the software, as long as the software meets the definitions of medical devices, should comply with the medical software regulations.

5. Product Description and Examples

(1) Hospital Administration Management Software

The administration management software is used individually in single hospital or may allow information exchange between medical entities. Those commonly seen are hospital information systems, electronic medical records, laboratory information systems, hospital financial record systems and so on. Such software systems are intended to replace paper records in keeping and checking patient information (such as identification number, medical record number, age, weight, appointment information, inspection results, doctors' reminders, schedule arrangement, treatment or transfer management, etc.). Although the aforementioned software may provide information to a healthcare professional as references, the ultimate clinical decision-making however relies primarily on the judgment and professional knowledge of the medical staff. Unless the software is intended to replace healthcare professionals in clinical decision-making, it may not be considered as a medical device.

[Example 1]

A software can convert the paper information into electronic format according to the medical records of the patients which are input by health professionals. When the patients are transferred to different medical institutions, these digitalized data can be easily read and used. Also, for exhibition or printing medical information, namely the medical records or related medical information (such as the patients' medical history or the instruction for use of the prescription medicine). When the software is not directly giving advice or diagnosing the diseases, the health professionals can still make the related assessments to decide whether to use the information for follow-up medical treatment, then the software is not considered a medical device.

(2) Medication Record Keeping and Dosage Calculation Software

Software intended to record patient medication history to be referenced by healthcare professionals will not be administered as a medical device if it is not intended to offer direct medication guidance to patients. Software intended to compile and convert the clinical drug handbooks of a healthcare professional into electronic versions, or simply calculate medication dosage based on patient weight, will also not be regarded as a medical device.

[Example 2]

A software provides suggestions to health professionals on the medicine usage, and the suggestions is completely the same with the Chinese IFU (instruction for use) of the medicines. Since the suggestions provide by the software are based on approved Chinese IFU, and displayed in electrical format, but not directly substituting the decision on medication made by the health professionals, and the health professionals still have to make their own determination, the software is not considered a medical device.

(3) General Wellness Software

Medical software which is used to maintain or improve health state or body function, does not promote wellness base on specific illness as general personal healthcare, such as weight management, physical fitness, products intended for recreational use, relaxation or stress management, mental acuity and sleep management, are not considered as medical devices, since they are not for medical purpose. Software and applications are used to display, transfer, and store measurements of personal health indicators (Weight, blood pressure, heart rate and blood glucose levels), or implement diet records, calculate energy consumption, count step numbers, execute action cycles, estimate the menstrual cycle of a woman and measure general heart rate or blood oxygen level. These functions do not include disease diagnose and treatment, hence are not considered as medical devices. But if a software is intended to process information generated by medical devices, such as the ones imbedded in the electronic blood pressure devices or in the blood glucose monitors for the purpose of signal processing or transfer, it will be administrated as a medical device.

Medical software or applications which are used to encourage, monitor or assist users to take a healthy lifestyle to reduce the risk of suffering from some chronic diseases, like those aimed to reduce the risk of getting diabetes, hypertension or high

cholesterol by diet, sleep control or exercise management, are not classified as medical device. Medical software or applications which are used to encourage, monitor or assist users to take a healthy lifestyle to improve the quality of life of patients who have already been diagnosed with chronic diseases or have related symptoms (not for treatment or to improve disease symptoms), for example to manage diet, sleep or exercise for patients with diabetes or hypertension, are not considered as medical device.

For those health promoting products, their potential risks shall be taken into account. Such as whether the product is implantable, invasive, or it has potential risk of causing the patient harm or illness, these attributes shall all be considered.

[Example 3-1]

A software can be used on recording the living and physical index of the infant (such as diaper changing, sleeping, height and weight), medical record (such as medical history, vaccination record, medication record), and provides information on health education (such as allergy, healthcare). Since the software is transforming the medical healthcare information from the medical institutions to e-format, and the suggestions it provides are within the care guideline announced by relevant health organization, and has no potential of harm, the software is not considered a medical device.

[Example 3-2]

A software provides suggestions and lifestyle assessments or records and tracks relevant data for identified users, in order to advance or maintain the fitness, health or wellness of the user. For example, the function of the software includes encouraging healthy diet, workout, weight loss or any other suggestions which promote a healthy lifestyle (such as diet diary, diet plan, calorie calculator for food, calorie calculator for workout, recording daily activities), or help tracking the sleeping pattern and quality. Since the software is aimed to encourage, record or assist the user to gain a healthier lifestyle, it is not considered a software.

(4) Medical Image Processing Software

Software simply intended to transfer and to store of medical images generated by diagnostic devices, such as X-ray, CT, MRI, or to display the aforementioned images for diagnostic purposes, will be administrated as CLASS 1 Medical Device, as enlisted in Regulations for Governing the Management of Medical Devices: “P.2010 Medical Imaging Storage Device” and “P. 2020 Medical Imaging Transfer Device”. If the medical software is intended to be used as a processing tool for medical images, and provides functions in image processing, handling, editing, and analyzing, it will then be administrated as a CLASS 2 Medical Device, as inscribed in Regulations for Governing the Management of Medical Devices under the Classification Sections “P.2050 Picture Archiving and Communication System (PACS)” and “P. 2030 Medical Imaging Digital Medical Imaging Device”.

(5) Computer-Aided Detection / Diagnostic Software

Computer-Aided Detection (CADe) software is intended to process and handle the information generated by diagnostic medical imaging devices (such as by ultrasound, X-ray, CT and MRI), physical signal (such as electroencephalogram EEG,

electrocardiography ECG) or pathological examination (such as tissue sections, biochemical test data), and further generate diagnostic or therapeutic indicators, images and graphs which mark, identify the lesions and assist in the detection of pathological changes or abnormalities. As CADe is intended to support medical professionals in diagnoses and treatments, it will be classified as a CLASS 2 Medical Device.

Aside from the supports that CADe can provide as described above, Computer-Aided Diagnosis (CADx) software is intended to evaluate the conspicuous lesions, such as benign or malignant pathological changes and pathological developments, and based on the numeric outputs to propose to medical professionals ailment diagnoses, risk assessment and subsequent treatment.If CADx is only intended to provide diagnostic references and suggestions, the ultimate clinical decisions will still be made by clinicians' own judgment, then CADx will be classified as a CLASS 2 Medical Device. If the CADx software is intended to replace medical professionals in decision making and offers direct diagnosis and treatment, it will be classified as a CLASS 3 Medical Device.

Computer Aided Trigae Software is used to rapidly filter out certain diseases regarding of the symptoms. For example, by using it to screen out patients with intracerebral hemorrhage, can assist healthcare professionals to reduce repeated clinical procedure. These software and applications are classified as CLASS 2 Medical Device, some exceptions are listed in Regulations for Governing the Management of Medical Devices

(6) Surgery Planning Software

Medical software intended to assist in the establishment of treatment plans and methods, able to prompt treatment methods and execute diagnostic evaluations, thereby to generate the therapeutic plans and postulate the therapeutic outcomes, such as "Radiation Therapy Planning Software" which simulates patient conditions under radiation treatment, calculates dosage absorption and distribution of body tissues, will be classified as a CLASS 2 Medical Device and administered under Classification Section "P. 5050 Medical Radioactive Treatment Systems Carrying Electrical Discharge". Surgery guiding / planning software may process and analyze information generated from imaging equipment and inspection instruments, simulate operation processes and outcomes, assist in the selection of surgical methods and calculate the parameters of the surgical instruments needed in the operation. Such software is used in neurosurgery, plastic surgery, otolaryngology, spine surgery, ophthalmology, and orthopedics. Due to its intended functions as a support, guidance to the surgeons during surgical operations, such software will be administered as a CLASS 2 Medical Device. In addition, the software for planning dental implant intended to process images generated from imaging diagnostic devices (e.g. CT), display tooth and implant locations, simulate and assess implant treatment, is also administered as a CLASS 2 Medical Device.

(7) **Patient Vital Sign Monitoring Software**

Certain medical software is in conjunction with various physiological monitoring instruments, such as patient surveillance systems, to monitor the vital signs of the

patients. The application program automatically takes measurements or receives data from a fixed medical device, assists a healthcare professional to monitor physiological conditions of a patient while alarms the care personnel if necessary. Such software is classified as a CLASS 2 Medical Device.

(8) **Long-Distance Medical Service and Healthcare Software**

Long distance medical and healthcare service uses long-range communication technology to provide health services or information. The medical devices are often used at home or out of the care centers to monitor the health conditions of the afflicted, to monitor the vital signs (blood pressure, blood oxygen level, heart beat), receive and transmit data from the devices to the healthcare professionals to observe the condition of the afflicted. Long-distance medical and caring functions may be imbedded in the servers, or be used in tandem with gateways and routers. If the software is only intended for data transmission, it will not be regarded as a medical device. If the software enables interpretation or analysis of devicederived information which will directly aid in diagnosis or treatment of a patient, the software will be administered as a CLASS 2 Medical Device.

(9) **Multiple Clinical Biochemical Indexes Analysis Software**

Medical software intended to aid in the clinical diagnosis, able to integrate results collected from external diagnostic equipment and other inspection instruments, calculate and interpret series of result, will be regarded as a medical device. For example, a software of pre-natal screening allows the analysis of blood biochemical indexes of a mother, the ultrasound indexes of her baby and other parameters, it enables statistic risk evaluations in the early pregnancy of birth defects, such as Down syndrome (trisomy 21), Edwards syndrome (trisomy 18) and neurological damages, hence the software will be administered as a CLASS 2 Medical Device.

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