Deciding When To Submit A 510(k) For A Change To An Existing Wireless Telemetry Medical Device; Final Guidance for FDA Reviewers and Industry

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Center for Devices and Radiological Health

Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

For questions regarding the use or interpretation of this guidance contact Thinh Nguyen, at 240-276-4010 or by electronic mail at thinh.nguyen@fda.hhs.gov.

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This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Purpose

The purpose of this document is to provide direction to manufacturers on deciding when to submit a 510(k) for a change to their existing wireless telemetry medical device or to a medical device incorporating wireless telemetry as a feature, as a result of the recent Federal Communication Commission (FCC) rule which designates certain frequency bands as "protected" bands for Wireless Medical Telemetry Service and establishes rules for their use.

Background

Under Parts 15 and 90 of Title 47 of the Code of Federal Regulations, wireless medical telemetry devices are allowed to operate on a secondary user basis in either the Private Land Mobile Radio Service (PLMRS) between 450 MHz and 470 MHz, or in vacant television channels 7 to 13 (174-216 MHz) and channels 14 to 46 (470-668 MHz, except in channel 37). Due to the emergence of digital television (DTV) and an increase in land mobile radio services, FCC is currently adopting changes that will allow more users to operate in these frequency bands. Because medical telemetry is a secondary user in these bands, the further crowding of these bands increases the potential for medical devices to be interfered with by other licensed primary users within the same bands. This potential problem was illustrated by two recent incidents where DTV broadcasting interfered with wireless telemetry cardiac monitors at two Dallas hospitals[1].

Since the occurrence of these incidents, efforts have been made by the Food and Drug Administration (FDA), the American Hospital Association, FCC, clinicians, and medical device manufacturers to provide a protected frequency spectrum specifically for wireless medical device telemetry. As a result, FCC is proposing a rule to allocate new frequency

bands in which wireless medical device telemetry would have primary status and to establish rules for their use. When the FCC's rule becomes effective, FDA recommends that wireless telemetry medical device manufacturers modify their existing devices to operate in these new protected frequencies as quickly as possible. To assist manufacturers in expediting these modified devices to the marketplace in the least burdensome manner, FDA is developing this guidance to help manufacturers decide whether the submission of a new 510(k) is required for change(s) made to their existing device and if required, the type of submission that should be submitted to FDA.

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be approved/cleared for marketing. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to comply with the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that information is being requested that is not relevant to the regulatory decision for your pending application or that there is a less burdensome way to address the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center webpage at:
http://www.fda.gov/cdrh/modact/leastburdensome.html

Scope

The type of modifications addressed in this draft guidance only include (1) performance specification changes that will enable existing wireless medical telemetry devices to operate in the newly allocated frequency bands and (2) technology changes that will enable the device to avoid interference. Any labeling changes that result from these changes should be permitted; however, this guidance document does not address changes to the device labeling such as intended uses, contra-indications for use, etc. Also, this guidance document does not address other specific types of technological changes to the device.

The three types of technology changes that are addressed in this guidance are:

1. Change in the transmitting frequency of the device;
2. Change in the device technology such that the device is able to operate in its intended environment without being interfered with regardless of the transmitting frequency; and
3. Change to the device as specified in 1 or 2 listed above and a change to add new features/functions to the device, or to remove/modify current features/functions of the device.

The decision as to whether the submission of a 510(k) is necessary for each of the changes listed above is based on current ODE policy as provided in Blue Book Memorandum #K97-1[2] entitled, "Deciding When to Submit A 510(k) for a Change to an Existing Device," dated January 10, 1997. This document is intended to aid 510(k) holders in deciding whether the changes they are about to make to their own existing device require the submission of a new 510(k).

Procedure

1. Change in the transmitting frequency of the device

Based on the Memorandum #K97-1 and the New 510(k) Paradigm Guidance Document[3], a change in the transmitting frequency and/or a change in the modulation technique of a wireless telemetry medical device will result in the following:

i. No new 510(k) submission is required if the design validation activities for this change do not raise new issues of safety and effectiveness.

ii. A new 510(k) submission is required if the design validation activities for this change raise new issues of safety and effectiveness.

A change in the transmitting frequency, with or without a change in modulation technique, would be considered a change in the device's performance specification. According to Memorandum #K97-1, this type of change will only result in the submission of a 510(k) if routine design validation activities either produce unexpected results or otherwise prove to be inadequate to validate the design change. This is because in such instances, questions of safety and effectiveness may be associated with the design change. If this is the case, submission of a new 510(k) is required, and may be a Special, Abbreviated, or Traditional 510(k).

2. Change in the device technology such that the device is able to operate in its intended environment without being interfered with regardless of the transmitting frequency.

This type of change would necessitate the submission of a new 510(k).

A change in technology of this type would be considered a change in the operating principle of the device and thus, would lead to a submission of a new 510(k). FDA generally considers this type of change to be a change in the fundamental scientific technology of the device, and thus, either an Abbreviated or Traditional 510(k) would be required.

3. Change to the device as specified in 1 or 2 listed above and a change to add new features/functions, or remove/modify current features/functions of the device.

This type of change could result in no new 510(k), a Special 510(k), an Abbreviated 510(k), or a Traditional 510(k).

It is not feasible for FDA to predict all of the types of changes that 510(k) holders may make to their device in addition to changing the device's transmitting frequency or the device technology. Similarly, FDA cannot prospectively determine whether a 510(k) is necessary for each of these changes. For this reason, we recommend that once a 510(k) holders determine whether changing the transmitting frequency of their device requires the submission of a new 510(k), they should evaluate each of the remaining changes separately and determine if any of these changes require a new 510(k). The decision should be based on the guidance provided in Memorandum #K97-1. If a new 510(k) is required for any of the modifications, then the 510(k) holder may choose to demonstrate substantial equivalence by submitting a Special, an Abbreviated, or a Traditional 510(k) as set forth in the New 510(k) Paradigm guidance document. If, after using the #K97-1 guidance, the 510(k) holder determines that a new 510(k) submission is not necessary, documentation of this decision should be placed in the device master record.

FDA Contact

For more information on the EMI concerns for medical telemetry and the determinations for the regulatory processes mentioned in this guidance, please contact Thinh X. Nguyen, at (301) 594-2186, ext. 152.

References

[1] FDA Public Health Advisory: Interference between digital TV transmissions and medical telemetry systems, March 20, 1998.

[2] Blue Book Memorandum #K97-1 entitled, "Deciding When to Submit a 510(k) for a Change to an Existing Device" dated January 10, 1997. This document is intended to aid device manufacturers in deciding whether the changes they are about to make to their own existing device require the submission of a new 510(k).

[3] CDRH/ODE Guidance entitled "The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications" dated March 20, 1998. This document is intended to provide guidance to the regulated industry and reviewers on two alternative approaches that may be used, under appropriate circumstances, to demonstrate substantial equivalence.