

# Guidance for Industry and FDA Staff

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## Class II Special Controls Guidance Document: Remote Medication Management System

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# Preface

## Public Comment

Written 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. Alternatively, electronic comments may be submitted to <http://www.fda.gov/dockets/ecomments>. Please identify your comments with the docket number listed in the notice of availability that publishes in the *Federal Register* announcing the availability of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

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## **Table of Contents**

1.	Introduction.....	1
	The Least Burdensome Approach .....	2
2.	Background.....	2
3.	The Content and Format of an Abbreviated 510(k) Submission .....	3
	Coversheet .....	3
	Proposed Labeling .....	3
	Summary Report.....	3
4.	Scope.....	5
5.	Device Description .....	6
	Device Components.....	6
	Photograph or Drawing of the Device.....	6
	Comparison to the Predicate Device .....	6
6.	Risks to Health.....	6
7.	Software Validation .....	7
8.	Simulated Use Testing .....	7
	Identification of the Medication .....	8
	Selection and Delivery of the Medication .....	8
	Verification of the Current Inventory of Medications.....	8
	Segregation of Medications.....	8
	Features Related to Drug Expiration .....	9
	Anomaly Reporting .....	9
	Power Backup Systems .....	9
	Information Security.....	9
	Patient Input and Control.....	10
	Hardware and Software Controls .....	10
9.	Electromagnetic Compatibility (EMC).....	11
10.	Electrical and Mechanical Safety Performance Testing.....	11
11.	Labeling .....	11
	Pharmacist’s Prescription Label .....	12

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*This guidance represents the Food and Drug Administration's (FDA'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 FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.*

### 1. Introduction

This guidance document was developed as a special control guidance to support the classification of the remote medication management system into class II (special controls). The device is intended to provide a means for a patient's prescribed medications to be stored in a delivery unit; to permit a healthcare professional to remotely schedule a patient's prescribed medications; to provide notification to a patient when the prescribed medications are due to be taken; to release the prescribed medications to a tray of the delivery unit accessible to a patient on the patient's command; and to provide to the healthcare professional a history of the event. The system is intended for use as an aid to healthcare professionals in managing therapeutic regimens for patients in the home or clinic. This guidance is issued in conjunction with a Federal Register notice announcing the classification of remote medication management systems.

Following the effective date of a final rule, manufacturers of remote medication management systems will need to address the issues covered in this special control guidance. However, the manufacturer need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

## **The Least Burdensome Approach**

The issues identified in this guidance document represent those we believe need to be addressed before your device can be marketed. 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 follow the guidance and address the issues we have identified. We believe we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe there is a less burdensome way to address the issues, you should follow the procedures outlined in the document **A Suggested Approach to Resolving Least Burdensome Issues**.<sup>1</sup>

## **2. Background**

FDA believes that special controls, when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of remote medication management system. Therefore, a manufacturer who intends to market a device of this generic type must (1) conform to the general controls of the Federal Food, Drug, and Cosmetic Act (the Act), including the premarket notification requirements described in 21 CFR 807 Subpart E, (2) address the specific risks to health associated with remote medication management system, and (3) obtain a substantial equivalence determination from FDA prior to marketing the device. (See also 21 CFR 807.85.)

This special control guidance document identifies the classification regulation and product code for the remote medication management system (refer to **Section 4. Scope**). Other sections of this guidance document list the risks to health FDA has identified and describe measures that, if followed by manufacturers and combined with the general controls, will generally address the risks associated with remote medication management system and lead to a timely premarket notification (510(k)) review and clearance. This document supplements other FDA documents regarding the content requirements of a 510(k) submission. When developing your submission, we recommend you also refer to CDRH's **Device Advice**,<sup>2</sup> 21 CFR 807.87, and **Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s**.<sup>3</sup>

As described in the guidance **The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications – Final Guidance**,<sup>4</sup> you may submit a Traditional 510(k), or you have the option of submitting either an Abbreviated 510(k) or a Special 510(k). FDA believes an Abbreviated 510(k) provides the least burdensome means of demonstrating substantial equivalence for a new device, particularly once a class II special controls guidance document has been issued. If you are

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<sup>1</sup> <http://www.fda.gov/cdrh/modact/leastburdensome.html>

<sup>2</sup> <http://www.fda.gov/cdrh/devadvice/>

<sup>3</sup> <http://www.fda.gov/cdrh/ode/guidance/1567.html>

<sup>4</sup> <http://www.fda.gov/cdrh/ode/parad510.html>

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considering certain modifications to one of your own cleared devices, you may lessen the regulatory burden by submitting a Special 510(k).

### **3. The Content and Format of an Abbreviated 510(k) Submission**

An abbreviated 510(k) submission must include the required elements identified in 21 CFR 807.87, including the proposed labeling for the device sufficient to describe the device, its intended use, and the directions for its use. In an Abbreviated 510(k), FDA may consider the contents of a summary report to be appropriate supporting data within the meaning of 21 CFR 807.87(f) or (g). The report should describe how this special control guidance document was used during the device development and testing and should briefly describe the methods or tests used and a summary of the test data or description of the acceptance criteria applied to address the risks identified in this document, as well as any additional risks specific to your device. This section suggests information to fulfill some of the requirements of section 807.87 as well as some other items that we recommend you include in an Abbreviated 510(k).

#### **Coversheet**

The coversheet should prominently identify the submission as an Abbreviated 510(k) and cite the title of this guidance document.

#### **Proposed Labeling**

Proposed labeling should be sufficient to describe the device, its intended use, and the directions for its use. Refer to **Section 11. Labeling** for specific information to be included in the labeling for devices covered by this guidance document.

#### **Summary Report**

We recommend the summary report contain the following:

##### **Description of the device and its intended use**

We recommend the description include a complete discussion of the performance specifications, and when appropriate, detailed, labeled drawings of the device. Refer to **Section 5. Device Description** for specific information we recommend you include in the description of your device. FDA also recommends you submit an “indications for use” enclosure.<sup>5</sup>

##### **Description of device design requirements**

We recommend you include a brief description of the device design requirements.

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<sup>5</sup> Refer to <http://www.fda.gov/cdrh/ode/indicate.html> for the recommended format.

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### **Identification of the risk analysis method**

We recommend you identify the risk analysis method(s) you used to assess the risk profile in general, your specific device's design, and the results of this analysis. Refer to **Section 6. Risks to Health** for the risks to health FDA has identified as generally associated with the use of this device.

### **Discussion of the device characteristics**

We recommend you discuss the device characteristics that address the risks identified in this guidance document and any additional risks identified in your risk analysis.

### **Description of the performance aspects**

We recommend you include a brief description of the test method(s) you have used or intend to use to address each performance aspect identified in **Sections 7–10** of this guidance document. If you follow a suggested test method, you may cite the method rather than describing it. If you modify a suggested test method, you may cite the method, but we recommend you provide sufficient information to explain the nature of and reason for the modification. For each test, you may either (1) briefly present the data resulting from the test in clear and concise form, such as a table, **or** (2) describe the acceptance criteria that you will apply to your test results.<sup>6</sup> (See also 21 CFR 820.30, Subpart C – Design Controls for the Quality System Regulation.)

### **Reliance on standards**

If you choose to rely on a recognized standard for any part of the device design or testing, you may include either a:

- statement that conformance assessment to specified acceptance criteria will be performed before the product is marketed; or
- declaration of conformity to the standard.<sup>7</sup>

Because a declaration of conformity is based on results of a conformance assessment, we believe you cannot properly submit a declaration of conformity

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<sup>6</sup> If FDA makes a substantial equivalence determination based on acceptance criteria, we recommend the subject device be tested and shown to meet these acceptance criteria before being introduced into interstate commerce. If the finished device does not meet the acceptance criteria and thus differs from the device described in the cleared 510(k), FDA recommends you apply the same criteria used to assess modifications to legally marketed devices (21 CFR 807.81(a)(3)) to determine if marketing of the finished device requires clearance of a new 510(k).

<sup>7</sup> See **Required Elements for a Declaration of Conformity to a Recognized Standard (Screening Checklist for All Premarket Notification [510(k)] Submissions**, <http://www.fda.gov/cdrh/ode/reqrecstand.html>.

## *Contains Nonbinding Recommendations*

until you have completed the testing that the standard describes. For more information, please refer to section 514(c)(1)(B) of the Act and the FDA guidance **Use of Standards in Substantial Equivalence Determinations**.<sup>8</sup>

If it is not clear how you have addressed the risks identified by FDA or additional risks identified through your risk analysis, we may request additional information about aspects of the device's performance characteristics. We may also request additional information if we need it to assess the adequacy of your acceptance criteria. (Under 21 CFR 807.87(l), we may request any additional information that is necessary to reach a determination regarding substantial equivalence).

As an alternative to submitting an Abbreviated 510(k), you may submit a Traditional 510(k) that provides all the information and data required under 21 CFR 807.87 and described in this guidance. A Traditional 510(k) includes all your methods, data, acceptance criteria, and conclusions. If you are considering certain modifications to one of your own cleared devices, you may submit a Special 510(k).

The general discussion above applies to any device subject to a special controls guidance document. The following is a specific discussion of how we recommend you apply this guidance document to a premarket notification submission for a remote medication management system.

## **4. Scope**

The scope of this document is limited to the following class II device (product code NZH) described below.

### **21 CFR 880.6315 Remote Medication Management System.**

**Identification.** A remote medication management system is a device composed of clinical and communications software, a medication delivery unit, and medication packaging. The system is intended to store the patient's prescribed medications in a delivery unit; to permit a healthcare professional to remotely schedule the patient's prescribed medications; to notify the patient when the prescribed medications are due to be taken; to release the prescribed medications to a tray of the delivery unit accessible to the patient on the patient's command; and to record a history of the event for the healthcare professional. The system is intended for use as an aid to healthcare professionals in managing therapeutic regimens for patients in the home or clinic.

**Classification.** Class II (special controls). The special controls are: The FDA guidance document entitled: "Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Remote Medication Management System." See Sec. 880.1(e) for availability of this guidance document.

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<sup>8</sup> <http://www.fda.gov/cdrh/ode/guidance/1131.html>

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Daily activity assist devices, including medication reminder, product code NXQ, are not within the scope of this guidance. (21 CFR 890.5050)

## 5. Device Description

We recommend you identify your device using the regulation and product code described in **Section 4. Scope** and include the following:

### Device Components

We recommend you identify all components, system software, and accessories within the scope of the 510(k).

### Photograph or Drawing of the Device

We recommend you provide a photograph or drawing of the device. We also recommend you provide a functional block diagram (including all accessories).

### Comparison to the Predicate Device

We recommend you explain how your device and the predicate are similar, with respect to indications for use and technological characteristics.

## 6. Risks to Health

In the table below, FDA has identified the risks to health generally associated with the use of the remote medication management system addressed in this document. The measures recommended to mitigate these identified risks are given in this guidance document, as also shown in the table below. You should also conduct a risk analysis before submitting your premarket notification to identify any other risks specific to your device. We recommend the premarket notification describe the risk analysis method and include the results. If you elect to use an alternative approach to address a particular risk identified in this guidance document, or you have identified risks additional to those in the guidance, you should provide sufficient detail to support the approach you have used to address that risk.

Identified Risk	Recommended Mitigation Measures
Improper Dosage Delivered to Patient	7. Software Validation 8. Simulated Use Testing 11. Labeling
Cross-Contamination of Medications	8. Simulated Use Testing

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Compromised Information Security	7. Software Validation 8. Simulated Use Testing
Failure of the Device	7. Software Validation 8. Simulated Use Testing 11. Labeling
Electromagnetic Interference	9. Electromagnetic Compatibility 11. Labeling
Electrical and Mechanical Hazards	10. Electrical and Mechanical Safety Performance Testing 11. Labeling

## **7. Software Validation**

We recommend that you submit the information for software-controlled devices described in **Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.**<sup>9</sup> The kind of information we recommend you submit is determined by the “level of concern,” which is related to the risks associated with software failure. The level of concern for a device may be minor, moderate, or major. FDA believes that the software used to operate the device presents a “major level of concern” as described in the Software Guidance because there may be potential for a patient to miss necessary medication, or receive an incorrect dose of a drug or the wrong drug, which could lead to serious injury or death, if the device fails because of a software defect.

In addition, we recommend that the development of the control software follow IEC 60601-1-4: Medical electrical equipment – Part 1-4; “General Requirements for Safety; Collateral Standard: Programmable electrical medical devices” or equivalent methods.

## **8. Simulated Use Testing**

To test the functions and features of your device, we recommend you subject your device to simulated bench testing representing three years of patient use showing that the medication delivery unit functions reliably to:

- automatically reject the medication upon a failure to identify the medication;
- confirm selection and delivery of the proper medication;
- warn the user in the event of a failure, improper medication, or expired medication;
- verify the quantity of medication; and

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<sup>9</sup> <http://www.fda.gov/cdrh/ode/guidance/337.html>

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- warn the user upon failure of component used to verify medication quantity.

We recommend that you submit simulated use test plans, results, and summaries. Your simulated use testing should evaluate the performance of the features described below.

### **Identification of the Medication**

One source of medication error is the inability of patients to properly identify their medications. The medication delivery unit of the remote medication management system should identify the medication without relying upon the patient to accomplish this task. The medication delivery unit should identify the medications by reading the manufacturer's or pharmacist's label, e.g., by reading a bar code. If the device is unable to identify the medication, the device should not accept the medication and should warn the user that the medication is unidentifiable and cannot be used with the device.

### **Selection and Delivery of the Medication**

Because patients may rely on the device to properly deliver their medications, the electromechanical systems of the medication delivery unit should reliably discharge a medication at the prescribed time and in the prescribed dose. The device should also verify that the dose has been successfully delivered. In the alternative, the device should warn the user that medications have not been released as prescribed. The device should maintain a complete history log of the delivery events.

### **Verification of the Current Inventory of Medications**

The ability of the device to deliver the proper medication is dependent on the device's ability to identify each medication and verify that the number of the medications contained within the medication delivery unit is consistent with the scheduled therapy. The device should warn the user that there are insufficient medications contained in the medication delivery unit to deliver the medications prescribed during a pre-defined, which may be user-defined, dosing period. The device should also verify the specific quantity of each medication contained within it.

### **Segregation of Medications**

Medications in the device should not come into contact with the medication delivery unit or with other medications stored in the medication delivery unit. Cross-contamination between different medications, either through contact within the medication delivery unit or through medication residues in the medication delivery unit creates a potential for adverse reactions, especially if a medication is no longer used by the patient because an allergy to that medication developed or was discovered.

To eliminate any direct contact between medications or between a medication and the medication delivery unit, each dose of each medication should remain contained within a package until the patient actually receives the medications. Alternatively, the device

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should ensure that the medications do not come in contact with surfaces of the medication delivery unit where there may be residue from other medications.

### **Features Related to Drug Expiration**

The device should not accept medication that is past its expiration date. In addition, the device should warn the user when medication has expired and cannot be used with the device.

### **Anomaly Reporting**

The device's control software should provide a method of identifying and managing anomalies in the interactions between the various components of the device in a timely fashion. The device should also include an extensive real-time anomaly reporting system that logs and reports errors (including conditional successes) on all parts of the device (including, in particular, the medication delivery unit). You should describe how these errors will be addressed or corrected, e.g., during scheduled maintenance by field personnel.

### **Power Backup Systems**

A power failure may prevent a patient from removing his medications from the medication delivery unit or may disable the control software, leaving it unable to communicate with the medication delivery unit, adjust the dosing schedule, or monitor patient compliance.

We recommend that you supply a battery backup that maintains the ability of the medication delivery unit to communicate with the control software, and can continue to operate the medication delivery unit for a period of time. In addition, there should be a method for the patient to easily remove the medications from the medication delivery unit in the event that a power failure causes the unit to not operate. We recommend the device allow for manual removal or automatic ejection of all of the medication packages in the event that the battery power drops below a minimum operating power.

### **Information Security**

We recommend you describe how your software addresses information security. Information security is the process of preventing the modification, misuse or denial of use, or the unauthorized use of that information that is stored, accessed or transferred from your device to an external recipient. We recommend that your device address the following four components of information security described below: Confidentiality, Integrity, Availability, and Accountability (CIAA).

**Confidentiality** means data and information are being disclosed only to authorized persons, entities and processes at authorized times and in the authorized manner. (The assurance that no unauthorized users have access to the information.)

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**Integrity** means data and information are accurate and complete and have not been improperly modified.

**Availability** means data information and information systems are accessible and usable on a timely basis in the required manner. (The assurance that the information will be available when needed.)

**Accountability** means an authorized user is identified and authenticated before access.

### **Patient Input and Control**

We recommend that you limit patient control of the device. The device and its control software should be designed so that none of the interactions between the device and the patient involve the patient entering any information used in the management, scheduling, or identification of the medication.

### **Hardware and Software Controls**

Adequate hardware and software controls should be in place to ensure the device functions safely despite user errors. Three typical user error scenarios are described below. Although typical, these three scenarios do not constitute an exhaustive compilation of possible user errors. Your submission should describe the scenarios your hardware and software controls address.<sup>10</sup>

**Example 1.** The healthcare professional needs to change the dosing schedule after the patient has already received his medications from the device. This may occur if the device has a feature to allow patients to receive their medications in advance of the scheduled dosing delivery (e.g., a patient going out for the day and carrying his doses along to take at the proper times). Such a situation could result in the healthcare professional attempting to reschedule deliveries that have already been made. Adequate software controls should be in place to prevent changes in the dosing schedule for medications that have already been delivered. The device should also alert the healthcare professional that the patient has already received medications and the dosing change will not take place until the next scheduled dosing period.

**Example 2.** Before the medication package is inserted into the medication delivery unit, a dose is removed from the medication package and administered to the patient. (This is similar to a situation where a power failure causes the patient to manually administer his medications without the use of the medication delivery unit.) Adequate software and hardware controls should be in place to prevent the

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<sup>10</sup> We recommend you clearly describe user error scenarios such as these and the controls employed to address them in the device software and hardware validation plans and system integration plans in your design history records and the design and development process described in 21 CFR 820.30 Design Controls.

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medication delivery unit from attempting to deliver a dose that is missing from the package. The device should be capable of identifying whether medications are missing from the package.

**Example 3.** In the process of receiving a dose from the device, the patient drops the dose or otherwise irretrievably loses it before he can take it and the patient does not have an alternate source of a replacement dose. The device should allow the patient to remove the medication package from the medication delivery unit, manually administer a dose, and then reinsert the package into the unit without causing subsequent errors in dose delivery.

## **9. Electromagnetic Compatibility (EMC)**

We recommend that you demonstrate the EMC of the device by performing EMC testing as described in the following FDA- recognized standard or equivalent method.

- IEC 60601-1-2 (Second Edition, 2001) Medical electrical equipment - Part1: General requirements for safety; Electromagnetic compatibility - Requirements and Tests.

## **10. Electrical and Mechanical Safety Performance Testing**

We recommend that you demonstrate the electrical and mechanical safety of the device by performing electrical and mechanical safety testing as described in the following FDA- recognized standard or equivalent method.

- IEC 60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety.

## **11. Labeling**

The premarket notification must include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). The following suggestions are aimed at assisting you in preparing labeling that satisfies the requirements of 21 CFR Part 801.<sup>11</sup>

We recommend that instructions delineate the technological features of your device and how your device will be used by patients. We also recommend that the instructions encourage

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<sup>11</sup> Although final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of 21 CFR Part 801 before a medical device is introduced into interstate commerce. In addition, final labeling for prescription medical devices must comply with 21 CFR 801.109. Labeling recommendations in this guidance are consistent with the requirements of Part 801.

## *Contains Nonbinding Recommendations*

local or institutional training programs designed to familiarize professional users with the features of your device and how to use it in a safe and effective manner.

We recommend that you include a patient manual with each device. See **Guidance on Medical Device Patient Labeling**.<sup>12</sup>

Any important precautions and warnings should appear prominently in the patient manual and, to the extent possible, on the device itself. For example, you should include a prominent warning that the device should not be connected to an electrical outlet controlled by a wall switch because of the potential to turn off the device inadvertently.

### **Pharmacist's Prescription Label**

The information on the prescription label affixed by the pharmacist to the medication packaging may include information necessary in patient or self-care, such as the drug name, form and dose, drug expiration date, warnings, and drug and food interactions. We recommend this information remain available to the patient after the packaging has been inserted into the medication delivery unit. If possible, the device should display the prescription label when the device delivers each dose or allow the prescription label to remain fully visible to the patient at all times.

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<sup>12</sup> <http://www.fda.gov/cdrh/ohip/guidance/1128.html>