



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 13 2007

Mr. Christopher E. Bossi
INRange Systems, Incorporated
220 Lakemont Park Boulevard
Altoona, PA 16602

Re: K051338
INRange Remote Medication Management System
Evaluation of Automatic Class III Designation
Regulation Number: 21 CFR 880.6315
Classification: Class II
Product Code: NZH

Dear Mr. Bossi,

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition for classification of the INRange Remote Medication Management System. The System is intended for use under the supervision of a licensed healthcare practitioner to remotely deliver, manage, assess, alter dosing schedules, perform interventions, and/or monitoring a patient's therapeutic regimens and adherence to those regimens in an outpatient setting.

FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the INRange Remote Medication Management System, and substantially equivalent devices of this generic type into class II under the generic name, Remote Medication Management System. This order also identifies the special controls applicable to this device, entitled, "Class II Special Controls Guidance Document: Remote Medication Management System."

FDA identifies this generic type of device as:

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; for 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.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) for a device may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device.

On September 25, 2006, FDA filed your petition requesting classification of the INRange Remote Medication Management System into class II. The petition was submitted under section 513(f)(2) of the act. In accordance with section 513(f)(1) of the act, FDA issued an order on September 20, 2006, automatically classifying the INRange Remote Medication Management System in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, which was subsequently reclassified into class I or class II. In order to classify the INRange Remote Medication Management System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the petition, FDA has determined that the INRange Remote Medication Management System intended for use as an aid to

healthcare providers in managing therapeutic regimens for patients in the home or clinic, can be classified in class II with the establishment of special controls for class II. FDA believes that class II special controls provide reasonable assurance of the safety and effectiveness of the device.

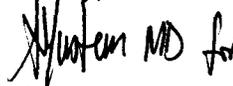
The potential risks to health associated with the device are: improper dosage delivered to patient; cross-contamination of medications; compromised information security; failure of the device; electromagnetic interference; and electrical and mechanical hazards. The special controls document aids in mitigating the risks by establishing performance and safety testing, and appropriate labeling.

In addition to the general controls of the act, the Remote Medication Management System is subject to the following special controls: Class II Special Controls Guidance Document: Remote Medication Management System. Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements. Thus, persons who intend to market this device must submit to FDA a premarket notification submission containing information on the Remote Medication Management System they intend to market prior to marketing the device and receive clearance to market from FDA.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market this device, subject to the general control provisions of the act and the special controls identified in this order. If you have any questions concerning this classification order, please contact Mr. Richard Chapman at 240-276-3706.

Sincerely,



Miriam C. Provost, Ph. D.
Deputy Director for Engineering
and Science Review
Office of Device Evaluation
Center for Devices and
Radiological Health