DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of Combination Products
15800 Crabbs Branch Way
Suite 200
Rockville, MD 20855

Food and Drug Administration
Rockville MD 20857

September 7, 2007

Caroline Lavoie
Director, Technical Service
Duoject Medical Systems, Inc.
50, Chemin de Gaspe, Complex B-5
Bromont, QC, Canada J2L 2N8

Re: Request for Designation
Smart-Rod™ Reconstitution System
Our File: RFD070041
Received: August 8, 2007
Filed: August 8, 2007

Dear Ms. Lavoie:

The Food and Drug Administration (FDA) has completed its review of the request for designation (RFD) for Smart-Rod™ Reconstitution System (Smart-Rod) that you submitted on behalf of Duoject Medical Systems, Inc. on August 8, 2007. The Office of Combination Products (OCP) filed the RFD on August 8, 2007. As explained below, we conclude that Smart-Rod is a device that will be regulated by the Center for Devices and Radiological Health (CDRH) under the device provisions of the Federal Food, Drug, and Cosmetic Act (the Act).

Product Description

As described in the RFD, Smart-Rod™ is a stand alone, single use device intended to transfer diluent contained in a pre-filled 1mL syringe to a vial containing a solid form of a drug product, and then return the admixture to the syringe without exposing the syringe needle. The RFD states that Smart-Rod™ is intended for use by physicians, nurses, other practitioners or patients who routinely administer injections of prescribed medication.

According to the RFD, Smart-Rod™ is comprised of a transfer needle, needle hub, plunger rod, spring, and vial socket. The syringe pre-filled with diluent for reconstitution is not part of Smart-Rod™; but must be separately obtained by the end user. The RFD states that to use Smart-Rod™, the user first attaches one end of Smart-Rod™ to the barrel of the pre-filled syringe and the other end of Smart-Rod™ to the vial holding the drug for reconstitution. By pushing the syringe downward through Smart-Rod™, the diluent is transferred from the syringe into the vial containing the drug. The vial now containing the drug and the diluent is rotated gently to mix the two together. The user then holds the vial upward and pulls the Smart-Rod™ until all the admixture is

transferred into the syringe. The syringe is detached from Smart-Rod™, and the admixture is delivered via the syringe to the patient.

The RFD recommends that because the Smart-Rod™ is intended to create an aseptic fluid path between a pre-filled syringe and a vial of drug, it be assigned to CDRH for review.

Product Classification: Device in CDRH

We have considered the information in the RFD and discussed the issues with staff in CDRH and the Center for Drug Evaluation and Research.

As described in the RFD, Smart-Rod™ is comprised of a transfer needle, needle hub, plunger rod, spring, and vial socket.[1] We conclude that Smart-Rod™ meets the definition of a device in that it is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.[2] Therefore, we conclude that the product is appropriately regulated by CDRH.

CDRH's General Hospital Devices Branch (GHDB) will be responsible for the premarket review and regulation of Smart-Rod™ under the device provisions of the Act. For further information about review requirements and how to proceed with submitting an application to CDRH, contact Anthony Watson, Branch Chief, GHDB, at 240-276-3707 or by email at anthony.watson@fda.hhs.gov. Please include a copy of this letter with your initial submission to CDRH.

If you have any questions about this letter, please contact me at 301-427-1934.

Sincerely,

Suzanne O'Shea
Product Classification Officer

cc: Anthony Watson

[1] We note that Smart-Rod™ does not include the pre-filled diluent syringe. If the product is redesigned to include a diluent for reconstitution, another jurisdictional determination will be required.

[2] Section 201(h) of the Act; 21 U.S.C. § 321(h).