JUL 21 2009

5I0 (K) SUMMARY **K090830**

Submitted By: Barbara Mornet

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Date: Jan 28, 2009

Device

Proposed Classification:

Regulation Name: Endoscope and accessories, Gastroenterology-Urology

Regulation Number: 21 CFR 876.1500

Regulatory Class: II

Product Code: FBK

Predicate Devices:

InjeTAK™ Adjustable Tip Needles are similar to:

The N-DO Endoinjector Needle (K043383)

The Cook Injection Needles (K022484),

K090830
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Device Description:

The injeTAK™ Adjustable Tip Needle consists of a metal needle cannula and an outer movable sheath with an attached adjusting mechanism.

The needle sheath diameter is 6Fr with 35-50cm in length, The stainless steel needle cannula is 25gauge

Needle tip length adjusting mechanism is used to adjust & set the relative distance between the distal needle point to the distal end tip of needle sheath in a range of 0-5 millimeter (mm).

Numbers (0, 2, 3, 5) printed on handle of the adjusting mechanism are used to indicate the individual needle tip (penetration) lengths in millimeter (mm) unit.

Substantial Equivalence:

Technologically speaking, the injeTAK™ Adjustable Tip Needle and predicate devices have similar intended uses and principles of action, there are both rigid and flexible needles intended to be accessories for common cystoscopes for the use of administering injection materials. They are all supplied sterile and are for single use only.

In conclusion the Laborie device, the injeTAK™ Adjustable Tip Needle, is substantially equivalent to the N-DO Endoinjector Needle by Physion and the Cook Injection Needles by Cook Urological in both their Intended Use and in physical respects.

Intended Use

The injeTAK™ Adjustable Tip Needles are intended to be used to deliver a variety of legally marketed drugs into tissues or structures during cystoscopic procedures. They are provided sterile for single use only.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Barbara Mornet
Regulatory Affairs Deputy
Laborie Medical Technologies
400 Avenue D, Suite 10
WILLISTON VERMONT 05495-7828

JUL 21 2009

Re: K090830
Trade/Device Name: injeTAK™ Adjustable Tip Needles, Models DIS196 and DIS198
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FBK
Dated: July 13, 2009
Received: July 15, 2009

Dear Ms. Mornet:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your devices are classified (see above) into either class II (Special Controls) or class III (PMA), they may be subject to additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation titled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090830

Device Name: injeTAK™ Adjustable Tip Needles

Indications For Use:
The injeTak™ Adjustable Tip Needles are intended to be used to deliver a variety of legally marketed drugs into tissues or structures during cystoscopic procedures. They are provided sterile and single use only.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K090830