K050688

APR 6 2005

## 510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

A. Submitter's Information:

| | |
|---|---|
| Submitter's Name: | C. R. Bard, Inc., Urological Division |
| Address: | 8195 Industrial Blvd.<br>Covington, Georgia 30014 |
| Contact Person: | Terri Morris |
| Contact Person's Phone: | (770) 784-6774 |
| Contact Person's Fax: | (770) 784-6419 |
| Date of Preparation: | March 10, 2005 |

B. Device Name:

| | |
|---|---|
| Trade Name: | Tegress™ Implant Needle |
| Common / Usual Name: | Endoscopic Needle |
| Classification Name: | Endoscope Accessory |

C. Predicate Device Name:

| | |
|---|---|
| Trade Name: | Genyx Flexible Injection Needle<br>#K001146 |

D. Device Description:

The Tegress™ Implant Needle is an accessory for currently marketed endoscopes and is used for the delivery of implantable materials into tissue during an endoscopic procedure.

The Tegress™ Implant Needle is a Transurethral Flexible Needle with Stabilizing Cannula that consists of a luer lock hub with one-way valve; a flexible catheter portion with longitundinal stripe; and a stainless steel non-coring needle at the tip. A full-length needle guard protects the needle catheter and tip. The Stabilizing Cannula consists of a semi-rigid catheter/tubing and Working Channel Seal. The Transurethral Needle and Stabilizing Cannula with Working Channel Seal are supplied sterile, non-pyrogenic and are compatible with DMSO.

E. Intended Use:

The Tegress™ Implant Needles are accessories for currently marketed endoscopes to allow delivery of injectable materials into tissues during an endoscopic procedure.

F. Technological Characteristics Summary:

The subject Tegress™ Implant Needle has the same intended use, design and fundamental scientific technology as the predicate device.

G. Performance Data Summary:

The Tegress™ Implant Needle referenced in this submission is held to the same design, manufacture, and performance specifications as those needles currently manufactured by Bard. The appropriate design verification and validation activities for the modifications to the Tegress™ Implant Needle were conducted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 6 2005

Ms. Terri Morris
Regulatory Affairs Specialist
C. R. Bard, Inc.
Bard Urological Division
8195 Industrial Blvd.
COVINGTON GA 30014-2655

Re: K050688
Trade/Device Name: Tegress™ Implant Needle
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FBK
Dated: March 16, 2005
Received: March 17, 2005

Dear Ms. Morris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is 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 device, 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 device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device 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 device complies 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|---|---|---|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K050688

**1.3** Indications for Use Statement

510(k) Number (if known): K050688

Device Name: Tegress™ Implant Needle

Indications for Use:

The Tegress™ Implant Needles are accessories for currently marketed endoscopes to allow delivery of injectable materials into tissues during an endoscopic procedure.

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

---

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1/2/96)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050688