AUG 24 1999

Summary of Safety and Effectiveness for the Rotatable Snare

K992477

submitted by

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Identification of a Legally Marketed Predicate Device

The InScope, LLC rotatable snares are substantially equivalent to the Microvasive Single-Use Polypectomy Snare, which are legally marketed and distributed by the Boston Scientific Corporation pursuant to 510(k) K950496.

Device Description

The InScope, LLC rotatable snare consists of an actuation handle, rotation handle and snare loop. The loop is attached to the actuation handle by means of a cable. A monopolar electrical connector is provided on the handle and is electrically connected to the snare loop. The rotation handle is positioned on the snare shaft and provides rotation control of the snare loop to aid in orienting the loop with respect to the polyp. Figure 1, Typical Rotatable Snare, shows several views of the rotatable snare.

The InScope, LLC rotatable snares may be used with most monopolar electrosurgical generators. The rotatable snare has a universal connector which is compatible with both Microvasive and Olympus active cord connectors.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 24 1999

Inscope, LLC
c/o Mr. Al Weisenborn
19526 East Lake Drive
Miami, FL 33015

Re: K992477
RotoSnare
Dated: July 23, 1999
Received: July 26, 1999
Regulatory Class: II
21 CFR §876.4300/Procode: 78 FDI

Dear Mr. Weisenborn:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

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510(k) Number (if known): K992477

Device Name Rotatable snare

Indications for Use:

The InScope, LLC rotatable snare is intended for the electrosurgical removal and cauterization of gastrointestinal tract polyps through an endoscope.

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)

David A. Syrmm
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K992477