Endoscopy Division
Smith & Nephew, Inc.
160 Dascomb Road, Andover, MA 01810 U.S.A.
Telephone: 508-749-1000
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Smith+Nephew

K980092

MAR - 9 1998

510(k) Summary
Smith & Nephew, Inc., Endoscopy Division
Dyonics InteliJet™ Reusable Cannula

Substantial Equivalence:

The material change defined in this premarket notification submission has no impact on the designed safety and efficacy of the Dyonics InteliJet Reusable Cannula. This conclusion is supported by the following testing: biocompatibility and flow curve analysis.

Predicate Device:

The predicate device for this submission is the currently marketed Dyonics InteliJet Reusable Cannula.

Summary of Device Function:

The Dyonics InteliJet Reusable Cannulas are used to establish portals to the surgical site during arthroscopic surgical procedures. The Dyonics InteliJet Reusable Cannulas are designed to work in conjunction with the InteliJet Fluid Management System to maintain intra-articular pressure for uniform distention and clear visualization of the surgical site.

Intended Use of Device:

The Dyonics InteliJet Reusable Cannulas are indicated for use with the Dyonics InteliJet Fluid Management System during arthroscopic surgical procedures of the knee, shoulder and small joints to regulate flow of irrigation fluids through the joint to maintain intra-articular pressure for uniform distention and clear visualization of the surgical site.

Comparison of Technological Characteristics of Predicate Device:

The basic technologies, design and function of the Smith & Nephew Dyonics InteliJet Cannulas are not changed by the material modification described in this Premarket Notification Submission. The material modification defined in this submission raises no new issues of safety and effectiveness.

Deborah J. Connors
Sr. Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 9 1998

Ms. Deborah J. Connors
Senior, Regulatory Affairs Specialist
Endoscopy Division
Smith & Nephew, Incorporated
160 Dascomb Road
Andover, Massachusetts 01810

Re: K980092
Trade Name: Smith & Nephew Dyonics Intelijet Reusable Cannulas
Regulatory Class: II
Product Code: FRN
Dated: January 8, 1998
Received: January 9, 1998

Dear Ms. Connors:

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 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 requirement, 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) 594-4595. 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/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number : K980092

Device Name : Smith & Nephew, Inc., Dyonics InteliJet™ Reusable Cannulas

Indications for Use :

The Dyonics InteliJet Reusable Cannulas are indicated for use with the InteliJet Fluid Management System during arthroscopic surgical procedures of the knee, shoulder and small joints to regulate flow of irrigation fluids through the joint to maintain intra-articular pressure for uniform distention and clear visualization of the surgical site.

(PLEASE DO WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980092

Prescription Use X OR Over-the-Counter ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)