

510(k) Summary *K974767*  
Smith & Nephew, Inc., Endoscopy Division  
Modification - Cleaning Instructions for Arthroscopes/ENT  
Endoscopes, Laparoscopes and Hysteroscopes

JAN 23 1998

**Substantial Equivalence:**

The modified cleaning instructions defined in this premarket notification submission have no impact on the designed safety and efficacy of the Dyonics Arthroscopes/ENT Endoscopes, Laparoscopes and Hysteroscopes. This conclusion is supported by the following testing: biocompatibility and residual chemical analyses.

**Predicate Device:**

The predicate devices for this submission are the currently marketed Dyonics Arthroscopes/ENT Endoscopes, Laparoscopes and Hysteroscopes.

**Summary of Device Function:**

The Dyonics Arthroscopes/ENT Endoscopes, Laparoscopes and Hysteroscopes are used during various minimally invasive endoscopic procedures to illuminate and visualize the surgical site.

**Intended Use of Device:**

The Dyonics® line of rigid Arthroscopes/ENT Endoscopes is indicated to provide illumination and visualization in diagnostic and operative arthroscopic surgical procedures and in endoscopic examination and treatment of the nasal cavities and nasal pharynx. In addition, the Dyonics 4mm diameter Arthroscopes/ENT Endoscopes are indicated for use in the removal of loose bodies and soft tissue within the hip joint as size/length appropriate.

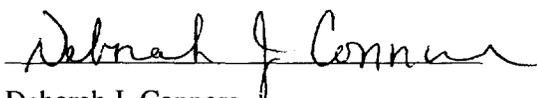
Dyonics Laparoscopes are indicated for use in laparoscopic surgical procedures to provide illumination and visualization of the surgical site.

The 5mm x 300mm Dyonics Laparoscope is also indicated for use in endoscopic surgery of superficial vessels and fascia of the lower extremities to provide illumination and visualization of the surgical site during decision, ligation and harvesting of vessels.

Dyonics Hysteroscopes are used to permit viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

**Comparison of Technological Characteristics of Predicate Device:**

The basic technologies, design and function of the Smith & Nephew Dyonics Arthroscopes/ENT Endoscopes, Laparoscopes and Hysteroscopes are not changed by the expanded cleaning instructions described in this Premarket Notification Submission. The expanded cleaning instructions defined in this submission raise no new issues of safety and effectiveness.



Deborah J. Connors  
Regulatory Affairs Specialist



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 23 1998

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

Re: K974767  
Trade Name: Modification - Cleaning Instructions for Arthroscopes/ENT  
Endoscopes, Laparoscopes and Hysteroscopes  
Regulatory Class: II  
Product Code: GCJ  
Dated: December 19, 1997  
Received: December 22, 1997

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.

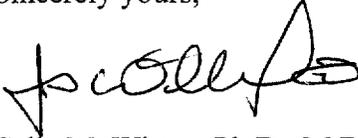
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice 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) 594-4595. 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 :

Device Name : Modification - Cleaning Instructions for Arthroscopes/ENT  
Endoscopes, Laparoscopes and Hysteroscopes

Indications for Use :

The Dyonics® line of rigid Arthroscopes/ENT Endoscopes is indicated to provide illumination and visualization in diagnostic and operative arthroscopic surgical procedures and in endoscopic examination and treatment of the nasal cavities and nasal pharynx. In addition, the Dyonics 4mm diameter Arthroscopes/ENT Endoscopes are indicated for use in the removal of loose bodies and soft tissue within the hip joint as size/length appropriate.

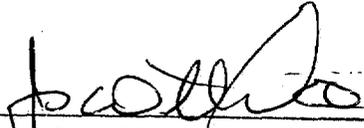
Dyonics Laparoscopes are indicated for use in laparoscopic surgical procedures to provide illumination and visualization of the surgical site.

The 5mm x 300mm Dyonics Laparoscope is also indicated for use in endoscopic surgery of superficial vessels and fascia of the lower extremities to provide illumination and visualization of the surgical site during decission, ligation and harvesting of vessels.

Dyonics Hysterosocpes are used to permit viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

(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 \_\_\_\_\_

2974767

Prescription Use    
(Per 21 CFR 801.109)

OR

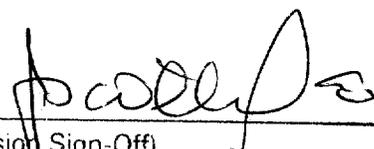
Over-the-Counter \_\_\_\_\_

(Optional Format 1-2-96)

Indicators for use page 2 K974767

The abrasive cleaning agent is provided as an accessory to the Dyonics Arthroscopes/ENT Endoscopes, Laparoscopes and Hysteroscopes and is intended to be used, when required, to remove deposits on optical surfaces thus maintaining optical integrity and allowing the scopes to perform as per their intended uses.

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number           K974767