

AUG 12 1997

K970511

**Endoscopy Division**

Smith & Nephew, Inc.  
160 Dascomb Road, Andover, MA 01810 U.S.A.  
Telephone: 508-749-1000  
Telefax: 508-749-1599

**510(k) Summary**  
**Smith & Nephew, Inc.**  
**Endoscopy Division**  
**Dyonics Curved Small Joint Disposable Endoscopic Surgery Blades**

**Smith+Nephew**

**Substantial Equivalence:**

The Smith & Nephew, Inc., Endoscopy Division Dyonics Curved Small Joint Disposable Endoscopic Surgery Blades are substantially equivalent in intended use, materials, design and function to small joint/ENT curved blades offered by Stryker Endoscopy for use with the Hummer and Hummer II Systems. Dyonics Curved Small Joint Disposable Endoscopic Surgery Blades are also substantially equivalent in intended use, materials, design and function to the Linvatec Merlin line of bendable disposable blades which are intended for use in arthroscopy and FESS procedures. Smith & Nephew, Inc., Endoscopy Division, Stryker Endoscopy and Linvatec provide blunt tip arthroscopic surgery blades in curved configurations. All blades have lateral cutting windows, in various diameters, lengths, and cutting window configurations. All blades are designed to run in conjunction with a control console, motor drive unit, footswitch, and a suction system under endoscopic video visualization.

**Predicate Device:**

The predicate devices for this submission are Stryker Endoscopy's Curved Small Joint/ENT Disposable Blades and the Linvatec Melin Disposable Arthroscopic Surgery Blade.

**Summary of Device Function:**

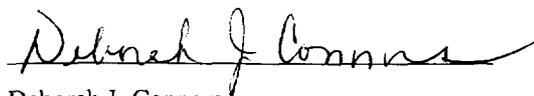
Curved Small Joint Disposable Endoscopic Surgery Blades are utilized in conjunction with a control console, motor drive unit, footswitch and suction to resect soft and osseous tissues as per indications. The blades can be operated in forward, reverse and oscillate modes and at variable speeds controlled by the surgeon. The rotary action coupled with suction draws tissue into the window of the blade where rotation of the inner blade cleanly excises and evacuates the resected material. Irrigation aids in evacuation of resected materials through the blade.

**Intended Use of Device:**

The Dyonics Disposable Endoscopic Surgery Blades are indicated for resection of soft and osseous tissues in large articular cavities, small articular cavities, and Functional Endoscopic Sinus Surgery (FESS). The FESS indication is limited to those small blades which are appropriate for the procedure.

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

The basic design and function of the Dyonics line of Curved Small Joint Disposable Endoscopic Surgery Blades is consistent with the Dyonics curved blades designs as described in previous submissions. These designs, function and intended use are substantially equivalent to those for curved small joint/ENT blades marketed by Stryker Endoscopy and the Linvatec Merlin "bendable" arthroscopy blade. The addition of the features defined in this premarket notification submission present no new safety or effectiveness concerns for the device.



Deborah J. Connors  
Regulatory Affairs



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

AUG 12 1997

Re: K970511  
Trade Name: Dyonics Disposable Endoscopic Surgery Blades  
Regulatory Class: II  
Product Code: HRX  
Dated: May 21, 1997  
Received: May 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.

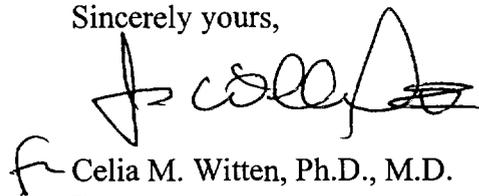
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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,

A handwritten signature in black ink, appearing to read 'C. Witten', with a stylized flourish at the end.

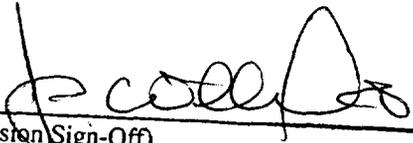
Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use Statement

*Indications for Use:* Dyonics Disposable Endoscopic Surgery Blades are indicated for resection of soft and osseous tissues in large articular cavities, small articular cavities, and Functional Endoscopic Sinus Surgery (FESS). The FESS application is limited to those small blades which are appropriate for the procedure.

*Contraindications:* The 2.0mm and 2.9mm TurboWhisker® and 2.9mm Cutter are contraindicated for FESS applications.

  
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(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K970511

Prescription Use X  
(Per 21 CFR 801.109)