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**Endoscopy Division**

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

**Smith+Nephew**

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K971676

JUN 27 1997

**510(k) Summary**  
**Smith & Nephew, Inc., Endoscopy Division**  
**Limited Reuse Endoscopic Surgery Blades**

**Substantial Equivalence :**

The Smith & Nephew, Inc., Endoscopy Division Limited Reuse Endoscopic Surgery Blades were originally determined to be substantially equivalent to predicate devices under 510(k) K955914.

**Predicate Device :**

The modification to the devices referenced in this 510(k) notification as compared to the predicate devices is the addition of a validated sterilization method and inclusion of test data showing that burr devices will meet all performance and safety standards when run at 8000 rpm.

**Summary of Device Function :**

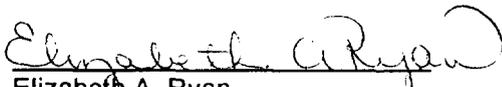
Limited reuse instrument consisting of several concentric tubes and various tip designs. The blades are used to resect and remove tissue endoscopically. The inner blade is driven by a motor. Tissue is removed by suction through the inner diameter of the inner blade.

**Intended Use of Device :**

Indicated for use during endoscopic resection of soft and osseous tissue in various large and small articular cavities. These blades are for limited reuse. The actual number of reuses will be dependant on proper care and use of the blade by the healthcare facilities.

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

The design and function of the items referred to in this 510(k) notification are identical to those listed in the previous limited reuse endoscopic surgery blade 510(k)s submitted by The Smith & Nephew, Inc., Endoscopy Division.

  
Elizabeth A. Ryan  
Regulatory Affairs



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 27 1997

Ms. Elizabeth A. Ryan  
Regulatory Affairs  
Smith & Nephew, Inc.  
Endoscopy Division  
160 Dascomb Road  
Andover, Massachusetts 01810

Re: K971676  
Trade Name: Limited Reuse Endoscopic Blades  
Regulatory Class: II  
Product Code: HRX  
Dated: May 6, 1997  
Received: May 7, 1997

Dear Ms. Ryan:

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

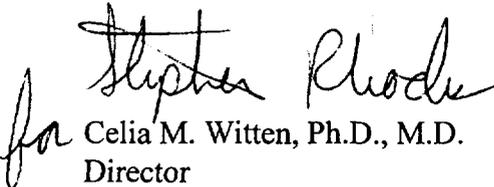
Page 2 - Ms. Elizabeth A. Ryan

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,

A handwritten signature in black ink, appearing to read "Celia M. Witten".

for 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 : K971676

Device Name : Limited Reuse Endoscopic Surgery Blades

Indications for Use :

The Smith & Nephew, Inc., Endoscopy Division Limited Reuse Endoscopic Surgery Blades as indicated for use during endoscopic resection of soft and osseous tissue in various large and small articular cavities. These blades are for limited reuse. The actual number of reuses will be dependant on proper care and use of the blade by healthcare facilities.

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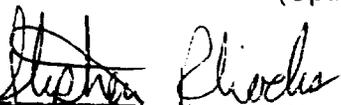
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR

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

(Optional Format 1-2-96)

  
(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K971676