

**SECTION 2. SUMMARY AND CERTIFICATION****A. 510(k) Summary**

NOV 02 2001

**Submitter:** SterilMed, Inc.

**Contact Person:** Patrick Fleischhacker  
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**Date Prepared:** August 6, 2001

**Trade Name:** SterilMed Reprocessed Powered Arthroscopic Accessories

**Classification Name and Number:** Arthroscope, Class II, 21 CFR 888.1100

**Product Code:** HRX

**Predicate Device(s):** The reprocessed powered arthroscopic accessories are substantially equivalent to:

- The powered arthroscopic accessories included in the Linvatec Universal Drive System (K971059);
- The Smith & Nephew Dyonics Disposable Endoscopic Surgery Blades (K970511);
- The Smith & Nephew Dyonics Disposable Arthroscopic Blades (K953695); and
- Their counterparts from the original manufacturers.

**Device Description:** SterilMed's reprocessed powered arthroscopic accessories consist of surgical instruments which run at variable speeds and are used for cutting soft tissue, cartilage and bone. These accessories are straight or angled, and have rotating blades that are used with irrigation and suction. Their diameters range from 2.0 to 6.0 mm and come in burr, shaver, and cutter designs. These accessories are designed to run in conjunction with a control console, motor drive unit, foot or hand switch, and a suction /irrigation system under endoscopic/video visualization. However, this submission only pertains to the accessories and not the other system components, such as the control console or motor drive unit.

**Intended Use:**

Reprocessed powered arthroscopic accessories are intended for use in operative large and small joint arthroscopic procedures and Functional Endoscopic Sinus Surgery (FESS). These accessories are indicated for resection of soft, osseous and cartilaginous tissue, and bone in large and small articular cavities and FESS.

**Functional and Safety Testing:**

Representative samples of reprocessed powered arthroscopic accessories underwent bench testing to demonstrate substantially equivalent functional characteristics. Process validation testing was done to validate the cleaning and sterilization procedures as well as the device packaging. In addition, the manufacturing process includes visual and functional testing of all products produced.

**Conclusion:**

The powered arthroscopic accessories reprocessed by SterilMed are substantially equivalent to the powered arthroscopic accessories included in the Linvatec Universal Drive System (K971059), the Smith & Nephew Dyonics Disposable Endoscopic Surgery Blades (K970511), the Smith & Nephew Dyonics Disposable Arthroscopic Blades (K953695), and their counterparts from the original manufacturers. This conclusion is based upon the fact that these devices' are essentially identical to their predicate devices in terms of functional design, materials, indications for use, and principles of operation.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Patrick Fleischhacker  
Vice President Regulatory  
and Quality Control  
SterilMed, Inc.  
11400 73<sup>rd</sup> Avenue North  
Minneapolis, Minnesota 55369

NOV 02 2001

Re: K012536

Trade/Device Name: SterilMed Reprocessed Powered Arthroscopic Accessories  
Regulation Number: 888.1100  
Regulation Name: Arthroscope  
Regulatory Class: II  
Product Code: HRX  
Dated: August 6, 2001  
Received: August 7, 2001

Dear Mr. Fleischhacker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

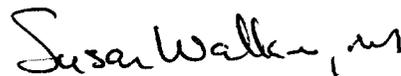
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,



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

Enclosure

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K012536

## Indications for use Page

**Device Name:** Reprocessed Powered Arthroscopic Accessories

### **Indications for Use:**

Reprocessed powered arthroscopic accessories are intended for use in operative large and small joint arthroscopic procedures and Functional Endoscopic Sinus Surgery (FESS). These accessories are indicated for resection of soft, osseous and cartilaginous tissue, and bone in large and small articular cavities and FESS.

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K012536