



DEC 27 2005

K053447

**510(k) Summary**

**ArthroCare Corporation  
ArthroCare® PercD™ SpineWand™**

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**General Information**

**Submitter Name/Address:** ArthroCare Corporation  
680 Vaqueros Avenue  
Sunnyvale, CA 94085-2936

**Establishment Registration Number:** 2951580

**Contact Person:** Valerie Defiesta-Ng  
Director, Regulatory Affairs

**Date Prepared:** December 9, 2005

**Device Description**

**Trade Name:** ArthroCare® PercD™ SpineWand™

**Generic/Common Name:** Electrosurgical Device and Accessories

**Classification Name:** Electrosurgical Cutting and Coagulation  
Device and Accessories (21 CFR  
878.4400)

**Predicate Devices**

ArthroCare PercD SpineWand K030954

**Product Description**

The Wands are bipolar, single use, high frequency electrosurgical devices.

**Intended Use**

The Perc-D™ SpineWand™ is indicated for ablation, coagulation, and decompression of disc material to treat symptomatic patients with contained herniated discs.

**Substantial Equivalence**

This Special 510(k) proposes modifications in materials for the ArthroCare PercD SpineWand, which were previously cleared under K030954 on April 16, 2003. The indications for use, technology, principle of operation, performance specifications, packaging, and sterilization parameters of the SpineWands remain the same as in the predicate cleared 510(k).

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**Summary of Safety and Effectiveness**

The modified SpineWands, as described in this submission, are substantially equivalent to the predicate SpineWands. The proposed modification in materials are not substantial changes or modifications, and do not significantly affect the safety or efficacy of the devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 27 2005

Ms. Valerie Defiesta-Ng  
Director, Regulatory Affairs  
ArthroCare Corporation  
680 Vaqueros Avenue  
Sunnyvale, California 94085-3523

Re: K053447  
Trade/Device Name: ArthroCare® PercD™ SpineWand™  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical cutting and  
Coagulation device and accessories.  
Regulatory Class: II  
Product Code: GEI  
Dated: December 9, 2005  
Received: December 9, 2005

Dear Ms. Defiesta-Ng:

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.

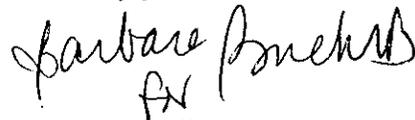
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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.

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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is written in a cursive style with a large "M" and "N".

Mark N. Melkerson  
Acting Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use Statement**

510(k) Number: K 053447

Device Name: ArthroCare® Perc-D™ SpineWand™

Indications for use:

The Perc-D™ SpineWand™ is indicated for ablation, coagulation, and decompression of disc material to treat symptomatic patients with contained herniated discs.

Prescription Use	<input checked="" type="checkbox"/>	AND/OR	Over-the-Counter Use
(Part 21 CFR 801 Subpart D)	_____		_____
			(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Suzanne Bruchins for MXM*  
**(Division Sign-Off)**  
**Division of General, Restorative,  
and Neurological Devices**

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