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K011279

# 510(k) Summary of Safety and Effectiveness
# ArthroCare, Corporation
# ENTec® EVac™ Plasma Wand™

## General Information

**Manufacturer:** ArthroCare, Corporation
595 North Pastoria Avenue
Sunnyvale, CA 94085-2936

**Establishment Registration Number:** 2951580

**Contact Person:** Bruce Prothro
Vice President Regulatory Affairs, Quality Assurance, and Clinical Research

**Date Prepared:** June 22, 2001

## Device Description

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

**Trade Name:** ENTec® EVac™ Plasma Wand™

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

## Predicate Devices

- ENTec® Coblator™ Plasma Surgery System — K973478
- Ethicon Powerstar Bipolar Scissors — K981361
- Coherent VersaPulse Select Single Wavelength (Ho:YAG) Dual Wavelength (Ho:YAG/Nd:YAG) Laser System — K990947

## Intended Use

The EVac Plasma Wand is indicated for ablation, coagulation, and hemostasis of soft tissue in tonsillectomy and adenoidectomy procedures.

## Product Description

The EVac Plasma Wand is a single use, disposable bipolar electrosurgical device designed to be used in conjunction with the ENTec Coblator Plasma Surgery System.

## Substantial Equivalence

In establishing substantial equivalence to the predicate devices, ArthroCare evaluated the indications for use, materials, technology, product specifications, and energy requirements of those systems. Additionally, performance testing has been completed to demonstrate the safe and effective use of the EVac Plasma Wand in the removal of tonsillar and adenoid tissue. The performance testing and device comparison demonstrated that the subject devices are substantially equivalent to the predicate devices, and are safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Bruce Prothro
Vice President, Regulatory Affairs, Quality Assurance,
and Clinical Research
ArthroCare, Corporation
595 North Pastoria Avenue
Sunnyvale, California 94085

Re: K011279
Trade/Device Name: ENTec® Evac™ Plasma Wand™
Regulation Number: 878.4400
Regulatory Class: II
Product Code: GEI
Dated: April 26, 2001
Received: April 27, 2001

Dear Mr. Prothro:

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 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). 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) 594-4659. 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 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/dsma/dsmamain.html".

Sincerely yours,

for 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

# Indications Statement

Device Name: ENTec® EVac™ Plasma Wand™
510(k) Number: K01 1279

Indications for use:

The EVac™ Plasma Wand is indicated for ablation, coagulation, and hemostasis of soft tissue in tonsillectomy and adenoidectomy procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use ____
(Per 21 CFR 801.109)

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K 011279