# Premarket Notification 510 (k) Summary for the Odontosurge 4

APR 2 9 2003

## Submitter:

X O Care
James Dieroff, Official United States Agent
1100 S. Coast Highway, Ste 204
Laguna Beach, CA 92651

**Date Summary was prepared:** October 29, 2002

## Name of the device:

X O Odontosurge 4

## Identification of Predicate device:

ArthroCare Dental Electrosurgery System
ArthroCare Corporation
K962445

## Description of the device:

The X O Odontosurge 4 is a high frequency electrosurgery unit that is comprised of the following three principal components: Control Box, Handpiece and Cord, and seven different Electrodes contained in a separate case. The X O Odontosurge 4 is compact and easily portable. The X O Odontosurge 4 is a reusable electrosurgical unit that is used to cut and to coagulate soft tissue during procedures in all disciplines of dentistry. There is no software utilized in the operation of the X O Odontosurge 4.

## Intended use:

The X O Odontosurge 4 is intended for use in cutting (removing) soft tissue and controlling bleeding in the oral cavity during surgical procedures in all phases of dentistry, including prosthodontics, periodontics, endodontics, pedodontics, orthodontics, oral surgery, and routine restorative dentistry.

## Comparison of device characteristics to predicate:

The intended use, sterilization method, and mode of operation of the X O Odontosurge 4 are the same as the ArthroCare Dental Electrosurgery System. The difference between the two devices is the frequency of operation. However, X O Care believes that this operating frequency offers many convenience and safety advantages.

## Conclusion:

The intended use, general design, materials of fabrication, and performance of the X O Odontosurge 4 are the same as the predicate device, ArthroCare Dental Electrosurgery System and devices already on the market. Therefore, the X O Odontosurge 4 that is the subject of this 510 (k) is substantially equivalent to dental Electrosurgical units in interstate commerce prior to May 28, 1976.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 9 2003

X O Care A/S
C/O Mr. James Dieroff
Odonto-Wave
1100 South Coast Highway, Suite 204
Laguna Beach, California 92651

Re: K023672
Trade/Device Name: X O Odontosurge 4
Regulation Number: 21 CFR 872.4920
Regulation Name: Dental Electrosurgical Unit and Accessories
Regulatory Class: II
Product Code: EKZ
Dated: April 22, 2003
Received: April 23, 2003

Dear Mr. Dieroff:

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.

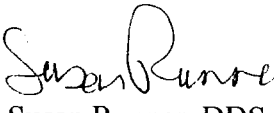
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4613. 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/dsma/dsmamain.html

Sincerely yours,



Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix G

**510 (k) Number:** K023672

None assigned as of this time

## Device Name:

X O Odontosurge 4

## Indications for Use:

The X O Odontosurge 4 is intended for use in removing soft tissue and controlling bleeding in the oral cavity in all phases of dentistry, including prosthodontics, periodontics, endodontics, pedodontics, orthodontics, oral surgery, and routine restorative dentistry.

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

X Prescription Use (per 21 CFR 801.109)

___ Over–the–counter (OTC) Use

Keri Mabry for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K023672