AUG 2 2 2001

# 510(k) Summary

## Ortho Development Corporation
## ORION-I EMF System

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K012129

A. Submitter:

Ortho Development Corporation
106 West 12200 South
Draper, UT 84020

Phone: (801) 553-9991
Fax: (801) 553-9993

Contact: Carol Freasier
Regulatory Affairs

Date Prepared: June 22, 2001

B. Device Names:

| | |
|---|---|
| Trade Name: | ORION-I EMF System |
| Common/usual Name: | Electrosurgical generator and accessories |
| Classification Name: | Electrosurgical and Coagulation Unit and Accessories |

C. Predicate Devices:

- Ellman Surgitron IEC II RF generator K001986, K001407
- ArthroCare System 2000 RF generator K001588, K992581
- Ellman Surgitron Hand-pieces K001986
- Kirwan Surgical Hand-pieces K982176
- Kirwan Surgical Electrodes K982176

D. Device Description:
The Ortho Development ORION-I EMF System is comprised of the ORION-I EMF generator and accessories, sterile, single-use hand-pieces and sterile, single-use electrodes. The ORION-I RF generator is a line-voltage powered, bipolar radiofrequency generator capable of delivering up to 16 watts of power at the electrode tip. The ORION-I utilizes controlled radiofrequency output for the electrocoagulation, cutting, and vaporization (ablation) of soft tissue during a variety of electrosurgical procedures in general surgical use, including orthopedic, arthroscopic, spinal, and neurosurgical procedures.

E. Intended Use:
The ORION-I EMF System is intended to be used for general surgical purposes in coagulation, cutting and vaporization (ablation) of soft tissues, including but not limited to orthopedic, arthroscopic, spinal, and neurosurgical procedures. Arthroscopic procedures may include those on the shoulder, elbow, wrist, hip, knee, and ankle. The ORION-I EMF System is intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

Contraindications
The use of the ORION-I EMF System is contraindicated, when in the judgment of the physician, an electrosurgical procedure would be contrary to the best interest of the patient.

F. Comparison with the Predicate Device:
There are no significant differences between the Ortho Development ORION-I EMF System and the predicate devices which would adversely affect the use of the device. The EMF System is substantially equivalent to the predicate devices in design, function, materials, and indications for use/intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 2 2001

Ortho Development Corporation
c/o Michael Kwan, Ph.D.
Principal Reviewer and Program Coordinator
Underwriters Laboratories, Inc.
1655 Scott Boulevard
Santa Clara, California 95050

Re: K012129
Trade/Device Name: ORION-1 EMF System
Regulation Number: 878.4400
Regulatory Class: II
Product Code: GEI
Dated: August 3, 2001
Received: August 10, 2001

Dear Dr. Kwan:

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 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,

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

510(k) Number (if known): K012129

Device Name: ORION-I EMF System

Indications for Use:

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Contraindications

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

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*Concurrence of CDRH, Office of Device Evaluation (ODE)*

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

for Mark N Milleman

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

(Optional Format 1-2-96)

510(k) Number K012129