JUL 2 1 1999

K991588

510(k) Summary
for
Swiss OrthoClast®

1. SPONSOR

EMS SA
Ch. de la Vuarpillière 31
CH-1260 Nyon
Switzerland

Contact Person: Gianni Campana
Telephone: 011 41 22 9944770

Date Prepared: May 5, 1999

2. DEVICE NAME

Proprietary Name:	Swiss OrthoClast®
Common/Usual Name:	Powered orthopedic surgical instrument
Classification Name:	Instrument, surgical, orthopedic, pneumatic powered and accessories

3. PREDICATE DEVICE

Ceboplane® (K933933)

4. INTENDED USE

The Swiss OrthoClast® is used for the removal of bone cement during implant revision surgery.

5. DEVICE DESCRIPTION

The EMS Swiss OrthoClast® system consists of a pressure regulator/control unit, pneumatic footswitch, handpiece, chisels of various sizes and shapes, a hollow drill and extractor for removal of the cement tip, and the Orthoscope. The Swiss OrthoClast® uses simple pneumatic and ballistic principles to fragment bone cement. A pressure pulse generated by the pressure regulator/control unit causes a moveable projectile in the handpiece to be driven forward to strike the proximal end of the chisel. The impact generates a shock wave along the chisel, which leads to a small, high-speed excursion of the chisel tip. The distal end of the chisel is

held in contact with the targeted cement. Repetitive shock waves result in fragmentation of the bone cement. A short tip excursion period followed by a longer rest period prevents the build-up of heat in the fragmentation site. Direct vision into body cavities, such as the femoral cavity, is facilitated using the Orthoscope.

6. PERFORMANCE TESTING

A comprehensive risk analysis was conducted to identify potential hazards associated with the use and misuse of the Swiss OrthoClast®. Verification tests conducted as a result of this risk analysis include the following

- Maximum excursion and velocity of the Swiss OrthoClast® chisel tips
- Handpiece and chisel longevity
- In vitro cement fragmentation efficiency
- Orthoscope temperature elevation

The results of these tests confirmed that the Swiss OrthoClast® met the design objectives as identified by the risk analysis.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The Swiss OrthoClast® has the same intended use as the Ceboplane®, that is, removal of bone cement during implant revision surgery. The Ceboplane® is a pneumatic powered reciprocating handpiece that accepts a wide variety of osteotome chisels. A fiberoptic illuminator mounts directly on the predicate handpiece to enhance visualization for working in deep cavities. Like the Swiss OrthoClast®, the Ceboplane® uses an internal piston hammer to deliver a high-energy, short-excursion impact to the desired location under the guidance of the surgeon using either single or multiple pulse mode. Both the OrthoClast® and the Ceboplane® require only one hand to operate, unlike the traditional osteotome and mallet which require two hands, allowing the surgeon to focus on the impact sight and precisely guide the chisel tip to its optimum position.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 1999

Ms. Shelia Hemeon-Heyer, Esq., RAC
Senior Staff Consultant
MDCI Representing EMS SA
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K991588
Trade Name: Swiss OrthoClast®
Regulatory Class: II
Product Code: HSZ, LZV, and GET
Dated: May 5, 1999
Received: May 7, 1999

Dear Ms. Hemeon-Heyer:

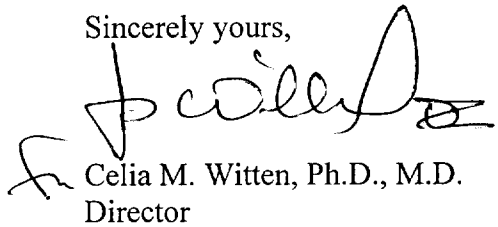
We have reviewed your Section 510(k) notification of intent to market the device referenced above, and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 control provisions of the Act. The general control 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 requirement, 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" (21 CFR 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/dsmamain.html".

Sincerely yours,



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

Enclosure

510(k) Number (if known): K991588

Device Name: EMS Swiss OrthoClast®

Indications For Use:

The EMS Swiss OrthoClast® is used for the removal of cement during implant revision surgery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991588

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

(Optional Format 1-2-96)