K994298

FEB 1 8 2000

SECTION 14: SUMMARY OF SAFETY AND EFFECTIVENESS

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

14.1 SUBMITTER INFORMATION

a. Company Name:	FRIADENT GmbH.
b. Company Address:	Steinzeugstrasse 50 Mannheim D-68229 Germany
c. Company Phone: Company Facsimile:	(011) 49 06 21 4 86 1549 (011) 49 06 21 4 86 1866
d. Contact Person:	Birgit Unger Quality Management and Regulatory Affairs
e. Date Summary Prepared:	December 17, 1999

14.2. DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	FRIOS MicroSaw
b. Classification Name:	Bone Cutting Instruments and Accessories 21 CFR 872.4120

14.3 IDENTIFICATION OF PREDICATE DEVICES

Company	Device	510(k) No.	Date Cleared
OsteoMed Corp.	OsteoPower System and Accessories	K971692	06/27/97

14.4 DEVICE DESCRIPTION

The FRIOS MicroSaw is a series of instruments used in preparing bone in dental and craniofacial surgical procedures. The MicroSaw components are used in

conjunction with the FRIOS Contra-Angle and Straight Handpieces. The MicroSaw consists of the disc for cutting bone, the drill for predrilling techniques and the chisel for elevating and luxating bone. The FRIOS MicroSaw also includes a protector which is attached to the handpiece which is designed to protect the soft tissue and limit the cutting depth.

14.5 SUBSTANTIAL EQUIVALENCE

The FRIOS MicroSaw is substantially equivalent to the OsteoMed Corporation OsteoPower System and Accessories cleared under premarket notification K971692 on June 27, 1997.

The fundamental technical characteristics of the FRIOS MicroSaw are similar to those of the predicate. The FRIOS MicroSaw is equivalent to the OsteoMed Corporation's OsteoPower System and Accessories in design, function and intended use.

14.6 INDICATIONS FOR USE

The FRIOS MicroSaw is indicated for use in preparing bone in conjunction with dental and craniofacial surgical procedures.

14.7 TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the FRIOS MicroSaw with the predicate device is provided within this submission. Both the FRIOS MicroSaw and the predicate device are similar in design, materials and functionality. The FRIOS MicroSaw cutting instruments are made of stainless steel and incorporate a standard latch lock for use with the FRIOS Straight and Contra-Angle Handpieces.

14.8 510(K) CHECKLIST

This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 8 2000

Friadent GmbH
c/o Ms. Carol Patterson
Consultant for Friadent GmbH
Patterson Consulting Group, Incorporated
21911 Erie Lane
Lake Forest, California 92630

Re: K994298
Trade Name: Frios MicroSaw
Regulatory Class: II
Product Code: KMW
Dated: December 20, 1999
Received: December 21, 1999

Dear Ms. Patterson:

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4692. 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number: K994298 To Be Assigned By FDA

Device Name: FRIOS MicroSaw

Indications for Use: The FRIOS MicroSaw is intended for use in preparing bone in conjunction with dental and craniofacial surgical procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K994298