JUL 30 1999

K991874

510(k) Summary
for
EMS Surface Mount Scaler

1. SPONSOR

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

Contact Person: Suzanne Fassio
Telephone: 022 994 47 00

Date Prepared: June 1, 1999

2. DEVICE NAME

Proprietary Name:	EMS Surface Mount Scaler
Common/Usual Name:	Ultrasonic Scaler
Classification Name:	Ultrasonic Scaler

3. PREDICATE DEVICES

EMS miniPiezon Ultrasonic Scaler K953026

4. INTENDED USE

The EMS Surface Mount Scaler is an ultrasonic scaler and is intended for the removal of supra and subgingival calculus deposits and stains from the teeth; periodontal pocket lavage with simultaneous ultrasonic tip movement; and scaling and root planing.

5. DEVICE DESCRIPTION

The EMS Surface Mount Scaler consists of a control unit housing containing the ultrasonic generator, a dental handpiece, scaler instrument, and torque wrench. The Scaler is designed to operate in conjunction with the office dental unit. The control unit housing is mounted under the control head of the dental unit and is connected to the

water supply, hanger air supply, pneumatic foot switch, and electrical supply of the dental unit. The Scaler ultrasonic power and water flow are simultaneously activated by pressing the dental unit foot switch. Power output and water flow can be adjusted using the knobs on the front of the Scaler. The Scaler handpiece is designed to be placed in the dental unit's handpiece hanger when not in use.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Surface Mount Scaler is substantially equivalent to the EMS miniPiezon ultrasonic scaler. Both devices are intended to be used for the removal of calculus deposits and stains from the teeth. The devices use the same ultrasonic generator and handpiece. The main difference between the devices is that the miniPiezon is a stand-alone ultrasonic scaler while the Surface Mount Scaler works in conjunction with the office dental unit. Minor differences in the user interface, and in the power, air, and water supplies, do not raise new questions of safety and effectiveness, leading to a conclusion of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 1999

(EMS SA) Electro Medical Systems
c/o Sheila Hemeon-Heyer, Esq., RAC
Senior Staff Consultant
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K991874
Trade Name: EMS Surface Mount Scaler
Regulatory Class: II
Product Code: ELC
Dated: June 1, 1999
Received: June 2, 1999

Dear Sheila Hemeon-Heyer, Esq., RAC:

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

510(k) Number (if known): _____

Device Name: EMS Surface Mount Scaler

Indications For Use:

The EMS Surface Mount Scaler is indicated for use in:

- Removal of supra and subgingival calculus deposits and stains from the teeth
- Periodontal pocket lavage with simultaneous ultrasonic tip movement
- Scaling and root planing

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Pamela Scott for Susan Runner
Division of Dental, Infection Control,
and General Hospital Devices
510(k) K991874

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

(Optional Format 1-2-96)