

JAN 27 2000

K992504

510(k) SUMMARY for
EMS KERMIT®

1. SPONSOR

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

Contact Person: Suzanne Fassio
Telephone: 022 994 47 00

Date Prepared: December 17, 1999

2. DEVICE NAME

Proprietary Name: EMS KERMIT®
Common/Usual Name: Ultrasonic Scaler
Classification Name: Ultrasonic Scaler

3. PREDICATE DEVICES

EMS miniPiezon	K953026
Piezon Master 400	K896749
KiS Microsurgical Instruments	
Sonicsys	
Amdent® US30	K920328

4. INTENDED USE

- removing supra and subgingival calculus and stains
- periodontal pocket lavage with simultaneous ultrasonic tip movement
- scaling and root planing
- releasing crowns, bridges, inlays and posts as wells as condensing gutta percha
- plugging for amalgam condensation
- amalgam burnishing
- preparing and rinsing root canals



JAN 27 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Cynthia J. M. Nolte, Ph.D., RAC
Staff Consultant
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K992504
Trade Name: EMS KERMIT®
Regulatory Class: II
Product Code: ELC
Dated: December 17, 1999
Received: December 20, 1999

Dear Dr. Nolte:

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 (Pre-market 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 pre-market notification submission does not affect any

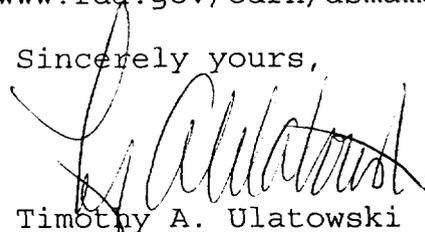
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obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

K992504

510(k) Number (if known):

Device Name: EMS KERMIT®

Indications for Use:

The EMS KERMIT® is an ultrasonic scaler which is intended for the following:

- Removing supra and subgingival calculus deposits and stains from the teeth
- Periodontal pocket lavage with simultaneous ultrasonic tip movement
- Scaling and root planing
- Releasing crowns, bridges, inlays and posts as well as condensing gutta percha
- Plugging for amalgam condensation
- Amalgam burnishing
- Preparing, cleaning, and irrigating root canals
- Preparing approximal cavities
- Cementing inlays and onlays
- Retrograde preparation of root canals

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Pinner

(Division Sign-Off)

Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K992504

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

EMS KERMIT®
Additional Information - K992504

12/17/99