

AUG 13 2002

K022328

**Special 510(k): Device Modification
510(k) Summary
for
Electro Medical Systems SA
EMS PIEZON[®] MASTER 600**

1. SPONSOR

ELECTRO MEDICAL SYSTEMS SA
Chemin de la Vuarpilliere 31
CH-1260 Nyon
Switzerland

Contact Person: Suzanne Fassio
Regulatory Manager

Date Prepared: July 17, 2002

2. Device Name

Trade/Proprietary Name: EMS Piezon[®] Master 600
Common/Usual Name: Ultrasonic Scaler
Classification Name: Ultrasonic Scaler

3. Predicate Devices

- Piezon Master 400 (K896749)
- EMS KERMIT[®] (K992504)

4. INTENDED USE

The EMS Piezon[®] Master 600 is an ultrasonic scaler intended for use in the following dental and periodontal applications:

- Removing supra and subgingival calculus deposits and stains from 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
- Cavity preparation
- Cementing inlays and onlays
- Retrograde preparation of root canals

5. DEVICE DESCRIPTION

The proposed Piezon[®] Master 600 is a modification of the Piezon[®] Master 400. The modified Piezon[®] Master 600 consists of the main scaler unit (including a peristaltic pump for irrigant delivery), hoses and connectors for two handpieces, a foot control containing a four-position switch, and two bottles for holding irrigation liquids. The Piezon[®] Master 600 is supplied with one of a number of optional Instrument Systems (containing a Universal handpiece and scaling instruments), a flat key, and a torque tool (CombiTorque) for attaching instruments to the handpiece.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The modifications made to the parent Piezon[®] Master 400 to produce the proposed EMS Piezon[®] Master 600 were implemented to enhance the procedural flexibility and improve the ease of use of the device. These modifications do not alter the general intended use or fundamental scientific technology of the device.

Both the proposed and parent devices are ultrasonic scalers intended for use in dental and periodontal cleaning, preparatory, and restorative procedures. The capability of the Piezon[®] Master 600 ultrasonic scaler was enhanced to include the cavity preparation, cementation of inlays and onlays, and retrograde preparation of root canals. These applications were cleared for use with the EMS KERMIT[®].

The overall design of the EMS Piezon[®] Master 600 is identical to the design of the unmodified Piezon[®] Master 400. The design modifications made to produce the EMS Piezon[®] Master 600 were implemented to improve the convenience and ease of use of the device and allow use of the Piezon[®] Master 600 with all instruments available for the EMS ultrasonic scaler product line. These design enhancements include the following:

- Enhanced ultrasonic performance
- Improved handpiece appearance and ergonomics
- Irrigation liquid flow control moved to the handpiece hose
- Selection of dry and wet work functions moved to foot control
- Addition of ultrasonic boost function to foot control
- Addition of three operating modes with different ultrasonic power ranges selectable from main scaler unit
- Availability of three irrigation sources including two irrigation bottles and external water supply

7. PERFORMANCE TESTING

The appropriate design verification and design validation activities were conducted to address the potential risks identified in the Hazard Analysis. These activities included electrical safety testing, electromagnetic compatibility testing, and the completion of Design Control Checklists to ensure that all design requirements were fulfilled. The results confirm that the modified EMS Piezon[®] Master 600 is safe and effective for the indicated dental and periodontal cleaning, preparatory, and restorative procedures.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 2002

Electro Medical Systems SA
C/O Ms. Cynthia J. M. Nolte
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K022328
Trade/Device Name: EMS Piezon® Master 600
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: July 17, 2002
Received: July 18, 2002

Dear Ms. Nolte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 Part 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,



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

Enclosure

510(k) Number (if known):

Device Name: EMS Piezon[®] Master 600

Indications for Use:

The EMS Piezon[®] Master 600 is an ultrasonic scaler intended for use in the following dental and periodontal applications:

- Removing supra and subgingival calculus deposits and stains from teeth
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- 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)



(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K022328

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)