MAR 2 9 2006

510(K) SUMMARY

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(K) number is: K060171.

1. **Submitter's Identification:**

DMETEC CO.,LTD.
#402-803 Techno-Park, 193 Yakdae-Dong, Wonmi-Ku,
Bucheon, Korea
Tel: +82-32-234-0011
Date Summary Prepared: January 20, 2006

2. **Name of the Device:**

Proprietary Name: Cleanse S+ Ultrasonic Scaler
Classification Name: Scaler, Ultrasonic, product code ELC
Classification: Class II, 21 CFR 872.4850

4. **Predicate Device Information:**

America Green Dent Cleanse S	K033044
EMS Mini Master	K953026
EMS Piezon Master 600	K022328
EMS miniPiezon	K953026

5. **Device Description:**

The Cleanse S+ is an ultrasonic scaler consisting of a main chassis containing an external electric power supply, controls for water flow and ultrasonic intensity, displays, and ultrasonic generator. The device is connected directly to a water supply for irrigation during use. A footswitch used for on/off control is connected to the main chassis by a footswitch cord. A handpiece is connected to the main chassis by a handpiece cord. Instruments (stainless steel tips) designed for specific dental procedure are attached to the distal end of the handpiece.

6. **Intended Use:**

- Removing supra and subgingival calculus and stains
- Periodontal pocket lavage with simultaneous ultrasonic tip movement
- Scaling and root planning
- 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

7. **Comparison to Predicate Devices**

Cleanse S Ultrasonic Scaler – identical in component materials, including the handpiece, the scaler tips, and the sterilization box. Differs from the predicate in that the Cleanse S+ is a different unit design with different control functions (analog vs.digital), indicator lamps, and footswitch lock

EMS MiniMaster, (K050710), and EMS Piezon Master 600 (K022328): Same indications for use.

EMS miniPiezon legally marketed by under K953026: The Cleanse S+ Ultrasonic cleaner is similar in design, operation, and performance:

	DMETEC(Cleanse S+)	**EMS(miniPiezon)**
UNIT		
Supply voltage	24V DC	24V AC
Supply frequency	-	50/60 Hz
Power consumption(max)	22W max	25W
Water supply pressure	1 to 5 bar(15 to 72 psi)	1 to 5 bar(15 to 72 psi)
OUTPUT CHARACTERISTICS		
Maximum output power with load	8W	8W
Frequency range available	24-32 kHz	25-32 kHz
TRANSFORMER		
Input	110-240 VAC, 50-60Hz	100/220 VAC/50-60Hz

Output	24V DC/ 1.7A	24V AC/ 1.25A
HANDPIECE AND TIPS	Reusable-Autoclavable	Reusable-Autoclavable

8. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Testing was conducted in accordance with IEC 60601-1:88+A1:91+A2:95 used in conjunction with EN 60601-1:90+A1/A12:93+A2/A13:96, and EN 55011:98+A1:99 and EN 60601-1-2:2001

9. **Discussion of Clinical Tests Performed:**

No clinical testing was conducted.

10. **Conclusions:**

The Cleanse S-- ultrasonic scaler is substantially similar to the predicates in intended use, operation, safety and function, and is effective for its' intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 9 2006

DMETEC Company Limited
C/O Ms. Carolann Kotula
Official Correspondent
MDI Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K060171
Trade/Device Name: Cleanse S+ Ultrasonic Scaler
Regulation Number: 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: January 20, 2006
Received: January 24, 2006

Dear Ms. Kotula:

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.

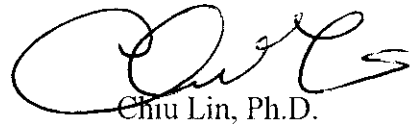
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4

Indications for Use

510(k) Number (if known): K060171

Device Name: Cleanse S+ Ultrasonic Scaler

Indications For Use: Intended for use during dental procedures to:

-Remove supra and subgingival calculus and stains
- Periodontal pocket lavage with simultaneous ultrasonic tip movement
- Scaling and root planning
- 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

Prescription Use __X_____ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page of

Susan Runner

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

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