OCT 28 1998

Summary of Safety and Effectiveness
for
AMD Piezo Tronic

1. Date Summary was Prepared

June 15, 1998

2. Submitter's Name and Address

Advanced Medical Devices
14 Canyon Creek Village, Suite 47
Richardson, Texas 75080

3. Contact Person

Mr. Greg Holland
Holland & Associates
3722 Ave. Sausalito
Irvine, CA 92606

Telephone: 949-262-0411
Telefax: 949-552-2821

4. Device Name

Trade/Proprietary Name: Piezo Tronic
Common Name: Ultrasonic Scaler
Classification Name: Ultrasonic Scaler

5. Predicate Devices

The legally marketed devices to which equivalence is being claimed are:

- Piezon Master 400, marketed by Electro Medical Systems SA
- Dentsply Bobcat® and Cavitron® Model 3000, both marketed by Dentsply International Inc. of York, PA 17405-0872

6. Device Description

The Piezo Tronic consists of a main chassis containing a water control valve, an electric power supply, controls and displays, and ultrasonic generator. A footswitch is connected to the main chassis by a footswitch cord and a handpiece containing an ultrasonic scaler tip is connected to the main chassis by a handpiece cord.

When a dental professional has placed the tip in the proper position, the footswitch is depressed which activates the ultrasonic generator and opens the control valve to initiate water flow. The water flow and the level of ultrasonic energy delivered can be adjusted via operator accessible controls. A circular knob with an inked line on the front panel indicates the power level currently selected. Power level is adjusted by rotating the labeled knob clockwise on the front panel. Water flow is adjusted via a knob also on the front panel. When the foot switch is released, both ultrasonic energy and water flow stop immediately.

Safety of the operator and patient is ensured by compliance to IEC 601-1 and EMC 89/336/CEE.

7. Intended Use

The Piezo Tronic is a device for delivering ultrasonic movement and water to a stainless steel tip that is used by a dentist or dental hygienist. The intended uses are:

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

8. Device Comparison

The ***Piezo Tronic*** is based on the Piezon Master 400 that was found substantially equivalent on August 31, 1990 (Premarket Notification K896749). The ultrasonic generator and the water delivery systems have by modified in this design, but the patient contact parts, the handpiece and the tip are functionally identical to the Piezon Master 400.

There are basically two differences between the ***Piezo Tronic*** and the Piezon Master 400. First, the Piezon Master 400 is designed to allow the use of antimicrobial irrigants. This is accomplished by using an electric pump to draw water from a bottle, to which antimicrobials can be added. The ***Piezo Tronic*** is not intended for use with antimicrobial irrigants and therefore gets its' water via a connection to the normal office water supply. Secondly, The Piezon Master 400 incorporates a two position foot switch to allow the user to select either water and ultrasound or ultrasound only. The ***Piezo Tronic*** has a single position footswitch that turns the water and ultrasound on together. In these respects the ***Piezo Tronic*** is similar to another currently marketed device, the Dentsply Cavitron Bobcat® Ultrasonic Scaler which also used tap water and incorporates a single position footswitch.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 28 1998

Advanced Medical Devices
C/O Mr. Greg Holland
Consultant to Advanced Medical Devices
3722 Avenue Sausalito
Irvine, California 92606

Re: K982793
Trade Name: Piezo Tronic
Regulatory Class: II
Product Code: ELC
Dated: August 7, 1998
Received: August 10, 1998

Dear Mr. Holland:

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): K982793

Device Name: Piezo Tronic

Indications For Use:

The Piezo Tronic is an ultrasonic scaler intended for use during dental cleaning and periodontal (gum) therapy to remove plaque and calculus deposits from teeth by application of an ultrasonic vibrating scaler tip to the teeth.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)