



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 28 2008

Bonart Company, Limited
C/O Mr. Eric L. Ong
Sales and Operations Manager
Bonart Medical Technology Incorporated
398 South Lemon Creek Drive, Suite L
Walnut, California 91789

Re: K081550

Trade/Device Names: Bonart-ART-P3II Multi-Function Piezoelectric Ultrasonic System wit Accessories (Tips)
Bonart ART-M3II Multi-Function Magnet Ultrasonic System with Accessories (Inserts)

Regulation Number: 21 CFR 872.4850

Regulation Name: Ultrasonic Scaler

Regulatory Class: II

Product Code: ELC

Dated: May 29, 2008

Received: June 3, 2008

Dear Mr. Ong:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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

K081550

INDICATION FOR USE

Applicant: Bonart Co., Ltd.
Rm.405, No.3 Wuchuan 1st Road
Hsinchuang, Taipei Hsien, Taiwan, R.O.C. (China)
FDA Registration Number: 9710363

510(k) Number: To be assigned by FDA

Device Name: Bonart ART-P3II Multi-Function Piezoelectric Ultrasonic system with accessories (tips)
Bonart ART-M3II Multi-Function Magnet Ultrasonic system with accessories (inserts)

Indication for Use:

ART-P3II Pro Multi-function piezoelectric Ultrasonic system is intended for use by medical professionals during dental cleaning and periodontal therapy to remove calculus and tartar deposits and stains from teeth using the application of an ultrasonically vibrating frequency through a stainless steel tip dental accessory called "Tip". Tip comes in various shapes (BS1, BS2, BS3 etc.) and is designed to generate a vibrating frequency of 29Khz.

ART-M3II Pro Multi-function Magnet Ultrasonic System is intended for use by medical professionals during dental cleaning and periodontal therapy to remove calculus and tartar deposits and stains from teeth using the application of an ultrasonically vibrating frequency through a stainless steel tip dental accessory called "Insert". Insert comes in various shapes (ART P-10, ART SL1-P100, ART IF50 etc.) and is designed to generate a vibrating frequency of 24.5KHz. ±5%.

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

RB Botz pres for Dr. Ranner
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081550

Concurrence of CDRH, Office of Device Evaluation (ODE)