K994203

MAR - 6 2000

SECTION 14: SUMMARY OF SAFETY AND EFFECTIVENESS

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

14.1 SUBMITIER INFORMATION

a. Company Name: BONART CO., LTD.

b. Company Address: RM.405, NO. 3 Wuchuan 1st Road, Sinchuan ,Taipei Hsien, Taiwan.

c. Company Phone: 886-2-22983980

Company Facsimile: 886-2-22983981

d. Contact Person: Bankson Tsai

e. Date Summary Prepared: Dec. 4 .1999

14.2. DEVICE IDENTIFICATION

a. Trade/Proprietary Name: ART Ultrasonic Scaler

b. Classification Name: Ultrasonic Scaler
21 CFR 872.4850

14.3 IDENTIFICATION OF PREDICATE DEVICE

Company	Device	510(k) No.	Date Cleared
TPC Advanced Technology ,Inc.	Power Plus Scaler	K983029	01/29/99
Tony Riso Co.	25/30 Multi-Function Ultrasonic Scaler	K964320	01/23/97

14.4 DEVICE DESCRIPTION

The BONART CO., LTD. ART Ultrasonic Scaler is available in two models: a 25 kHz power output and a 30 kHz power output. The Bonart ART comes equipped with a turbo mode and can be operated in scaling or perio mode functions. The Bonart ART Scaler is equipped with water adjustment and power adjustment. The unit is operated by a footswitch and comes complete with a handpiece. The handpiece is compatible with Cavitron and Bonart tips.

14.5 SUBSTANTIAL EQUIVALENCE

The Bonart ART Ultrasonic Scaler is substantially equivalent to the Power Plus Scaler in commercial distribution by TPC Advanced Technology Inc. and to the 25/30 Multi-Function Ultrasonic Scaler in commercial distribution by the Tony Riso Company.

The fundamental technical characteristics of the Bonart ART Scaler are similar to those of the predicate devices and are listed on the comparison charts provided in this 510(k) submission. The Bonart ART and the predicate devices function in the scaling and perio modes. There are 25 kHz and 30 kHz power output capabilities with the Bonart ART Scalers and the predicate devices. Power and water adjustment features are present in all units. The Bonart ART Ultrasonic Scaler and the predicate devices come equipped with handpieces and are compatible with Cavitron brand inserts.

14.6 INTENDED USE

The Bonart ART Ultrasonic Scaler is intended for use during dental cleaning and periodontal therapy to remove calculus deposits from teeth by application of an ultrasonic vibrating scaler tip to the teeth.

14.7 TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the Bonart ART Scaler with the predicate devices is provided within this submission. The Bonart ART Scaler and the predicate devices are composed of a scaling unit, handpiece, footswitch and inserts. The Bonart ART and predicate devices are compatible with Cavitron brand inserts. Both 25KHz and 30KHz power outputs are available with the Bonart ART and the predicate devices. Turbo functions, perio and scaling modes are also common to each of the units.

14.8 PERFORMANCE DATA

The Bonart ART Scaler was subjected to performance bench testing in accordance with applicable industry and clinical standards. Physical performance studies were conducted to verify that the Bonart ART Scaler conformed to all emission and immunity standards in accordance with EN and IEC regulations. Results of the testing showed that the Bonart ART Scaler performs as intended.

14.9 510(K) CHECKLIST

This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 6 2000

Mr. Bankson Tsai
General Manager
Bonart Co., Ltd.
Room 405, No. 3 Wuchuan 1st Road
Hsinchuang, Taipei Hsien
Taiwan

Re: K994203
Trade Name: ART Ultrasonic Scaler ART-M3
Regulatory Class: II
Product Code: ELC
Dated: December 4, 1999
Received: December 13, 1999

Dear Mr. Tsai:

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) 594-4690. 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

INDICATION FOR USE

510(k) Number : To Be Assigned By FDA

Device Name: BONART CO., LTD. ART Ultrasonic Scaler ART-M3

Indication for Use: The BONART CO., LTD. ART Ultrasonic Scaler is intended for use during dental cleaning and periodontal therapy to remove 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)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K994203

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)