K983029

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 SUBMITTER INFORMATION

a. Company Name:	TPC Advance Technology, Inc.
b. Company Address:	1422 S. Allec Street, #D Anaheim, CA. 92805
c. Company Phone: Company Facsimile:	(714) 758-9448 (714) 758-3950
d. Contact Person:	Chung-Liang Wang President
e. Date Summary Prepared:	August 28, 1998

14.2. DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	Power Plus Scaler
b. Classification Name:	Ultrasonic Scaler 21 CFR 872.4850

14.3 IDENTIFICATION OF PREDICATE DEVICE

Company	Device	510(k) No.	Date Cleared
Parkell	Turbo 25/30 Ultrasonic Scaler	K950256	04/04/95
Tony Riso Co.	25/30 Multi-Function Ultrasonic Scaler	K964320	01/23/97

14.4 DEVICE DESCRIPTION

The Power Plus Scaler is available in two models: a 25 kHz power output and a 30 kHz power output. The Power Plus comes equipped with a turbo mode and can be operated in scaling or perio mode functions. The Power Plus 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 TPC Advance Technology tips.

14.5 SUBSTANTIAL EQUIVALENCE

The Power Plus Scaler is substantially equivalent to the Turbo 25/30 Ultrasonic Scaler in commercial distribution by Parkell and to the 25/30 Multi-Function Ultrasonic Scaler in commercial distribution by the Tony Riso Company.

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

14.6 INTENDED USE

The Power Plus 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 Power Plus Scaler with the predicate devices is provided within this submission. The Power Plus Scaler and the predicate devices are composed of a scaling unit, handpiece, footswitch and inserts. The Power Plus and predicate devices are compatible with Cavitron® brand inserts. Both 25 kHz and 30kHz power outputs are available with the Power Plus and the predicate devices. Turbo functions, perio and scaling modes are also common to each of the units.

14.8 PERFORMANCE DATA

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

JAN 29 1999

TPC Advance Technology, Incorporated
C/O Ms. Carol Patterson
Consultant for TPC Advance Technology, Inc.
Patterson Consulting Group, Incorporated
18140 Smokesignal Drive
San Diego, California 92127

Re: K983029
Trade Name: Power Plus 25K Model, S1000, Power Plus 30K Model, S1001 Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: November 11, 1998
Received: November 12, 1998

Dear Ms. Patterson:

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 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). 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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" (21CFR 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/dsma/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: Power Plus Scaler

Indications for Use: The Power Plus 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)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K983029

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)