K033198

# 5. 510(K) SUMMARY

APR 3 0 2004

***APOZA* ULTRASONIC SCALER AND ENDODONTICS UNIT**

*Models:* ***SELECTOR U2***

***510K:***


Submitted by: APOZA ENTERPRISE CO., LTD.
6F, No.657, Chuang Cheng Road, Hsin-Chuang City, Taipei Hsien, China (Taiwan)

Contact person: General Manager
Mr. SHIH MIN-TEH


Date Summary Prepared: September 27, 2003

- Classification name: *Scaler, Ultrasonic*
- Classification number: *ELC, Class II*
- *Regulation Number:* *872.4850*
- Proprietary name: *APOZA ULTRASONIC SCALER AND ENDODONTICS UNIT, SELECTOR U2*
- Common name of device: *Ultrasonic Scaler*
- Predicate Device: *SATELEC SUPRASSON P5 BOOSTER*

  *510K No* ***K961158***

**Statement of Intended Use:** The Apoza Selector U2 is designed for the dentists to remove the calculus or stains on surface of teeth or clean the root canal ( with endo-kit) in the prophylaxis procedures. The device carries the following label:

*CAUTION: Federal (US) law restricts the use of this device to licensed professionals.*

**Comparison to Predicate Devices:** The ***APOZA Ultrasonic Scaler, Selector U2***, has been carefully compared to legally marketed devices with respect to intended use and technological characteristics. In addition, performance testing has been done to validate the performance of the device. The comparison and validation results presented in this 510k notification to the FDA show that the subject device is substantially equivalent to predicated device and is safe and effective in its intended use. We believe that the APOZA Ultrasonic Scaler, **Selector U2** is substantially equivalent to the predicate device, i.e., **SATELEC SUPRASSON P5 BOOSTER(K961158)**, and the data provided support the safety and effectiveness of Selector U2 for the intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 3 0 2004

Mr. Shih Min-Teh
Official Correspondent
Apoza Enterprise Company, Limited
6 F, No. 657, Chuang-Cheng Road,
Hsin-Chuang City,
Taipei Hsien,
CHINA (Taiwan) 242

Re: K033198

Trade/Device Name: Apoza Ultrasonic Scaler and Endodontics Unit, Selector U2
Regulation Number: 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: February 9, 2004
Received: February 17, 2004

Dear Mr. Min-Teh:

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.

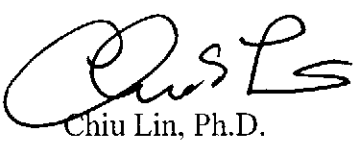
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4613. 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/dsma/dsmamain.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

K033198

# 4. INDICATIONS FOR USE STATEMENT

Applicant : APOZA Enterprise Co., Ltd.

510(k) Number : TO BE ASSIGNED

Device Name : **APOZA ULTRASONIC SCALER AND ENDODONTICS UNIT, SELECTOR U2**

## Indications for Use :

The Apoza Selector U2 is designed for the dentists to remove the calculus or stains on surface of teeth or clean the root canal ( with endo-kit) in the prophylaxis procedures.

The device carries the following label:

*CAUTION: Federal (US) law restricts the use of this device to licensed professionals.*

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter _____

Per 21 CFR 801.109 (Optional Format 1-2-96)

Robert S Betz for Dr Susan Runner

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

510(k) Number: K033198