K070373

510(K) SUMMARY

MAR 0 2 2007

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

1. Submitter's Name:	**APOZA ENTERPRISE CO. LTD.**
Address:	6 F, no.657, Chuang Cheng Road , 242 Hsin-Chuang City Taipei Hsien , Taiwan
Phone:	+886-2-29010620
Fax:	+886-2-29012208
Contact:	Mr. Shih Min-Teh

2. Device Name :

Trade Name:	APOZA LED Curing Light--also called APOZA Dental Curing Light -- (Family Model# E-MorLit , D-2000 , TOP 3W, TOP 5W)
Common Name:	Dental Curing Light
Classification name	activator, ultraviolet, for polymerization

3. DEVICE CLASS **APOZA LED Curing Light , also called APOZA Dental Curing Light , (Family Model# E-MorLit , D-2000 , TOP 3W, TOP 5W)** have been classified as

Regulatory Class: II
Panel: Dental
Product Code: EBZ
Regulation Number: 21CFR 872.6070

4. Predicate Device: The predicate device is the

- **LED Turbo-Pen (K#041303)** marketed by **APOZA ENTERPRISE CO. LTD.**

5. Intended Use: **APOZA LED Curing Light (Family: Model# E-MorLit , D-2000 , TOP 3W, TOP 5W)** with blue LED is a device which generating high intensity light for polymerization of light-curing materials used for dental curing purpose. Unlike Halogen light generating full light spectrum, it only emits light with wavelength mainly in the range of 440 to 490nrn, namely, the applicable range for dental curing of camphor quinine (CPQ) containing products.

6. Device Description:

APOZA LED Curing Light (Family: Model# E-MorLit , D-2000 , TOP 3W, TOP 5W) is non-invasive medical device and is designed for use in the optical polymerization of dental resins. **APOZA LED Curing Light** deliver 440-490nm blue light.

APOZA LED Curing Light is also called **APOZA Dental Curing Light.** it includes the following models:

- **E-MorLit** consist of a rechargeable Li-ion Battery (DC3.7V ; 2350mAH) in the handy unit and a switching power adaptor (also used as battery charger) ,
- **D-2000** consist of a rechargeable Li-ion Battery (DC3.7V ; 2350mAH) in the handy unit and a switching power adaptor (also used as battery charger)
- **TOP 3W** consist of a handy unit and a switching power adaptor.
- **TOP 5W** consist of a handy unit and a switching power adaptor.

The handy unit contains a programmed control circuit, high intensity dental blue LED light source, a light guide and a optical fiber that conduct light to the treatment area on the patient. The control circuit which governs the output power rate, timing and monitoring the temperature of the LED.

7. Performance Summary:

In terms of operating specification, Safety & EMC requirements, the device conforms to applicable standards included IEC 60601-1 and IEC 60601-1-2 requirements.

8. Conclusions:

APOZA LED Curing Light (Family: Model# E-MorLit , D-2000 , TOP 3W, TOP 5W) has the same intended use and technological characteristics as the **LED Turbo-Pen (K#041303)** previously marketed by the submitter -- **APOZA ENTERPRISE CO. LTD.**. Moreover, bench testing contained in this submission demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, **APOZA LED Curing Light (Family: Model# E-MorLit , D-2000 , TOP 3W, TOP 5W)** is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Apoza Enterprise Company, Limited
C/O Ms. Jennifer Reich
Harvest Consulting Corporation
2904 North Boldt Drive
Flagstaff, Arizona 86001

MAR 0 2 2007

Re: K070373
Trade/Device Name: APOZA LED Curing Light (Model# E-MorLit, D-2000, TOP 3W, TOP 5W) APOZA ENTERPRISE CO. LTD.
Regulation Number: 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ
Dated: January 25, 2007
Received: February 8, 2007

Dear Ms. Reich:

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.

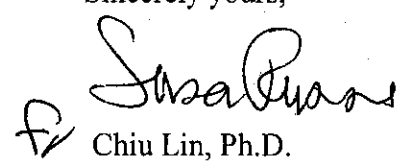
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
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Division of Anesthesiology, General Hospital,
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070373

Device Name: **APOZA LED Curing Light (Model# E-MorLit , D-2000 , TOP 3W, TOP 5W) APOZA ENTERPRISE CO. LTD.**

Indications For Use:

The **APOZA LED Curing Light** is a dental curing light that is designed for use in the optical polymerization of dental resins.

Prescription Use ___V___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runge

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

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