5. 510(K) SUMMARY

K060646

APR 21 2006

MONITEX INDUSTRIAL CO., LTD.

Models: Blue Luxcer, Curing Light M-830, M-835, M-855

510K:

- Submitted by: MONITEX INDUSTRIAL CO., LTD.
  6F, No.70, Guang-Fu Road, Sec. 1,
  San-Chung City, Taipei Hsien, 24158, Taiwan
- Official Correspondent: *Mr. Shu-Lung, Wang*
  General Management
- **510K Contact person:** *Dr. Jen, Ke-Min*
  No.58, Fu-Chiun Street,
  Hsin Chu City, 30067, Taiwan
  Tel: 886-3-5208829 Fax: 886-3-5209783
  Email: ceirs.jen@msa.hinet.net
- Classification name: *ACTIVATOR, ULTRAVIOLET, for POLYMERIZATION*
- Classification number: *EBZ, Class II*
- *Regulation Number:* *872.6070*
- Proprietary name: *Blue Luxcer,*
  Curing Light M-830, M-835, M-855
- Common name of device: *CURING LIGHT*
- Predicate Device: *APOZA ENTERPRISE CO., LTD.*
  LA500 Blue Light
  *510K No – **K033201***

Statement of Intended Use: *Blue Luxcer, Curing Light M-830, M-835, M-855*

The intended use of the *Blue Luxcer, Curing Light* is a visible curing unit programmed for the polymerization of light cure material by dental professionals.

Comparison to Predicate Devices: The *Blue Luxcer, Curing Light M-830, M-835, M-855*, have 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 are safe and effective in its intended use.

We believe that the *Blue Luxcer, Curing Light M-830, M-835, M-855* are substantially equivalent to the predicate device, i.e., APOZA CURING LIGHT, LA500 Blue Light in K033201, and the data provided support the safety and effectiveness for the intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 21 2006

Monitex Industrial Company, LTD
C/O Dr. Ke-Min Jen
No. 58, Fu-Chiun Street
Hsin Chu City, 30067 TAIWAN
REPUBLIC OF CHINA

Re: K060646
Trade/Device Name: Blue Luxcer Curing Light Models M-830, M-835, and M-855
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ
Dated: March 06, 2006
Received: March 10, 2006

Dear Dr. Jen:

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" (21 CFR 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 S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number: K060646

Device Name: MONITEX INDUSTRIAL CO., LTD.

Blue Luxcer, Curing Light M-830, M-835, M-855

- *Indications for use:*

This Blue Luxcer, Curing Light is a visible curing unit programmed for polymerization of light cured materials by dental professionals.

Prescription Use √ 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)

[signature]

... General H...

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