DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 8 2004

Mr. Ubiraci R Fernandes
General Manager
D.B.I America Corp
2909 Busch Lake Blvd,
Tampa, Florida - USA

Re: K041303
TradelDevice Name: Mega Light
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: 11
Product Code: EBZ
Dated: May 01, 2004
Received: May 17,2004

Dear Mr. Fernandes:

We have reviewed your Section 510(k) premarket notification ofintent 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 ofa 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 11 (Special Controls) or class III (PMA), it ma)!: 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.

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Indications for Use

510(k) Number (if known): K041303

Device Name: MegaLight
Indications for Use:

The LED MegaLight is a dental curing light that is designed for use in the optical polymerization of dental resins.

Prescription Use X___ AND/OR Over-The-Counter Use
(21 CFR Part 801 Subpart D) (21 CFR Part 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 Runner

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

510(k) Number: K041303