K060347

EXHIBIT 2

510(k) Summary

B&L Biotech Co., Ltd.
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Ansan-city,
Kyungki-do, Korea
Tel : 82-31-401-4757
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JUN - 5 2006

January 17, 2006

Contact: Inwhan Lee, Managing Director

1. **Identification of the Device:**
   Proprietary-Trade Name: B&L-Beta (Model: WL-B1)
   Classification Names: Dental Hand Instrument, Product code EKR
   Common/Usual Name: Heated Gutta Percha System

2. **Equivalent legally marketed devices:** Young OS LLC Obtura Heated Gutta Percha System, K042828

3. **Indications for Use (intended use)** Intended for use by professionally qualified Licensed dentists, endodontists and clinicians to heat gutta percha and to place it into the previously prepared root canals of human teeth, in order to provide a quick and complete obturation of the canal.

4. **Description of the Device:** The B& L-Beta(Model: WL-B1) is an electrically powered dental device used for heating gutta percha and placing the softened material in prepared root canals of teeth during root canal therapy. This model has a temperature memory controls. The user gently squeezes the trigger to express the desired amount of gutta percha in to the root canal through a soft silver applicator needle as the predicate, Obtura Heated Gutta Percha System(K042828)

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench and clinical testing indicates that the new device is as safe and effective as the predicate devices.

6. Substantial Equivalence Chart,

Characteristic	Young OS LLC Obtura (K042828)	B&L System (B&L-Beta Model: WL-B1)
Intended use	Intended for use by professionally qualified licensed dentists, endodontists and clinicians to heat gutta percha and to place it into the previously prepared root canals of human teeth, in order to provide a quick and complete obturation of the canal.	Intended for use by professionally qualified licensed dentists, endodontists and clinicians to heat gutta percha and to place it into the previously prepared root canals of human teeth, in order to provide a quick and complete obturation of the canal.
Power	12V DC 1A	3.7V Li-ion Battery
Adapter	DC 12V 1A powered from the AC line	DC 12V 850mA for charging, powered from AC line
Setting temp.	140, 150, 170, 180, 200°	100, 150,180, 200, 230 °
Needle size	21 G,23 G,25G	21, 23, 25G
Material of needle	Alloy of yellow copper, silver coated	Alloy of yellow copper, silver coated

7. Conclusion

After analyzing both bench and clinical testing data, it is the conclusion of B&L Biotech Co., Ltd that the B&L-Beta Model: WL-B1is as safe and effective as the predicate device, and have few technological differences, thus rendering them substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 5 2006

B&L Biotech Company, Limited
C/O Mr. Daniel Kamm
Regulatory Engineer
Kamm & Associates
P.O. Box 7007
Deerfield, Illinois 60015

Re: K060347
Trade/Device Name: B&L Beta, Model WL-B1
Regulation Number: 872.4565
Regulation Name: Dental Hand Instrument
Regulatory Class: I
Product Code: EKR
Dated: April 28, 2006
Received: May 8, 2006

Dear Mr. Kamm:

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.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060347

Device Name:

Indications For Use:
Intended for use by professionally qualified Licensed dentists, endodontists and clinicians to heat gutta percha and to place it into the previously prepared root canals of human teeth, in order to provide a quick and complete obturation of the canal.

Prescription Use X 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 Runner

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

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