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

Date: _____

1. Company and Correspondent making the submission:

   Name – We Dong Myung Industral Co.,Ltd.

   Telephone – 770-565-6166

   Fax – 770-565-9762

   Contact – Mr. Ronald D. Arkin

   Internet – http://www.dmdental.co.kr

2. Device :

   Proprietary Name – Apex90

   Common Name - Dental Alloy

   Classification Name – Gold-based alloys and precious metal alloys for clinical use

3. Predicate Device :

   Bio Herador SG, Jelenko Co.

   K003603

4. Classifications Names & Citations :

   21CFR 872.3060, EJT, Gold-based alloys and precious metal alloys for clinical use, Class2

   Guidance document for the preparation of premarket notifications [510(k)'s] for dental alloys

5. Description :

   Apex90 is a dental gold alloy for the fabrication of Porcelain-Fused-to-Metal Dental Crowns, Bridges, and implant-supported prosthesis substructures, which is composed of 98% of gold and platinum bearing gold color.

6. Indication for use :

   Reconstruction of porcelain-to-metal dental restorations/reconstruction of dental restorations.

7. Contra-indications :

Potential complications associated with the use of Apex90 may include, but not limited to:

- Allergies to metals

8. Review :

Apex 90 has the same device characteristics as the predicate device. Material, design and use concept is similar.

Apex 90 has been subjected to extensive safety, performance, and product validations prior to release. Safety tests have been performed to ensure the devices comply to applicable industry and US regulations.

An extensive review of literature pertaining to the safety and biocompatibility of dental gold alloy has been conducted. Appropriate safeguards have been incorporated in the design of Apex 90.

9. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, FDA's "Guidance document for the preparation of premarket notifications [510(k)'s] for dental alloys" and based on the information provided in this premarket notification We Dong Myung Dental Industrial Co.,Ltd. concludes that Apex 90 is safe and effective and substantially equivalent to predicate devices as described herein.

10. We Dong Myung Dental Industrial Co.,Ltd. will update and include in this summary any other information deemed seasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 9 2003

We Dong Myung Dental Industrial Company limited
C/O Mr. Chan Yo Won
Project Engineer
Underwriters Laboratories, Incorporated
2600 NW Lake Road
Camas, Washington 98607-8542

Re: K030206
Trade/Device Name: APEX 90
Regulation Number: 872.3060
Regulation Name: Gold-Based Alloys and Precious Metal Alloys for Clinical Use
Regulatory Class: II
Product Code: EJT
Dated: January 17, 2003
Received: January 21, 2003

Dear Mr. Won:

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,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K _____

Device Name: Apex90

Indication for use: Reconstruction of porcelain-to-metal dental restorations/reconstruction of dental restorations.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON AMOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21CFR801.109)

Kevin Mulloy -for NSR

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

510(k) Number K030206