AUG - 2 2004

K041378

510(K) SUMMARY

Submitter of 510(k): KoDent, Inc.
9778 Katella Ave. Ste.215, Anaheim, CA 92804
Phone: 714- 537-0600, Fax: 714- 537-0601

Contact person: Dae Kyu Chang
Phone: (714) 537-0600
Fax: (714) 537-0601
E-mail: KoDentinc@yahoo.com

Date of Summary: May 21, 20024
Trade name: BIO 60
Common: Gold cylinder for using UCLA Abutment
Classification name: Gold based alloys and precious metal alloys for clinical use
Product code: EJT
Classification: Class II

Legally marketed device: Southern Implants Cylinder
510(k) number:

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS

Test methods applied: as in ANSI/ADA 5 and ISO 9693

Comparison of composition:

Composition (weight)

	Au (%)	Pt (%)	Pd (%)	In (%)
Ceramicor	60.00	19.00	20.00	1.0
BIO 60	60.00	15.20	24.00	0.8

Comparison of physical and mechanical properties:

Alloy	Melting Point Range (°F)	Hardness (vickers)	Proof Strength (0.2%)	CTE ($x10^{-6}$/°C)	Density (g/c $x10m^3$)
Ceramicor	1,475	265	635N/mm $^{-2}$	12.0	18.5
BIO 60	1,400-1,490	250	645N/mm $^{-2}$	11.8	17.9

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 2 2004

Mr. Dae Kyu Chang
Owner
Kodent, Incorporated
9778 Katella Avenue, Suite 215
Anaheim, California 92804

Re: K041378
Trade/Device Name: BIO 60
Regulation Number: 21 CFR 872.3060
Regulation Name: Gold Based Alloys and Precious Metal Alloys for Clinical Use
Regulatory Class: II
Product Code: EJT
Dated: May 21, 2004
Received: May 24, 2004

Dear Mr. Chang:

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. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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,

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

Indications for Use

510(k) Number (if known): K041378

Device Name: BIO 60
Indications for Use:

BIO 60 is intended for use in the fabrication of implant superstructures and gold cylinders for dental implants.

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

Angela Blackwell for NSR

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

510(k) Number: K041378