K024144

510(K) SUMMARY

MAR 0 7 2003

Submitter of 510(k): SB LUCIUS, INC.
9778 Katella Ave. Ste. 205, Anaheim, CA 92804
Phone: (714) 530-2814, Fax : (714) 530-3448,

Contact person: Dae Kyu Chang
Phone: (714) 530-2814
Fax: (714) 530-3448
E-mail: Gatorkr@yahoo.co.kr

Date of Summary: Dec 15, 2002

Trade name: AIGIS-PT
Common: Dental casting alloy
Classification name: Gold based alloys and precious metal alloys for clinical use
Product code: EJT
Classification: Class II

Legally marketed device: AUROFLUID 2PF
510(k) number: K944572

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS

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

Comparison of composition:

COMPOSITION (WEIGHT, %)

Device Name	Au	Pt	Pd	Ag	CU	Zn	IR
AUROFLUID 2PF	78.0	1.0	-	11.5	8.50	-	<1.0
AIGIS-PT	77.4	1.3	1.0	11.0	7.12	1.0	0.08

Comparison of physical and mechanical properties:

Alloy	Melting Point Range (°F)	Hardness (Vickers)	Yield Strength (MPa)	Elongation (%)	Density (g/cm3)
AUROFLUID 2PF	1,705-1,768	125	260	40	16.0
AIGIS-PT	1,807-1,868	143	220	33	16.3

Discussion:

Since the composition of the legally marketed alloy and the new device is very similar, it may be assumed that the biological compatibility of the alloys is also very similar.

Conclusion:

The main elements and their concentration are almost identical. AIGIS-PT is an inlay, onlay, crown and bridge alloy. This device is dependable 77% gold alloy with a high gold appearance. AIGIS-PT is excellent for inlays, three-quarter crowns, long and short-span bridges. AIGIS-PT is substantially equivalent to AUROFLUID 2PF and the minor differences between them do not affect safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 7 2003

Mr. Dae-Kyu Chang
SB LUCIUS, Incorporated
9778 Katella Avenue, Suite 205
Anaheim, California 92804

Re: K024144
Trade/Device Name: AIGIS-PT
Regulation Number: 872.3060
Regulation Name: Gold-based Alloys and Precious Metal Alloys for Clinical Use
Regulatory Class: II
Product Code: EJT
Dated: December 15, 2002
Received: December 16, 2002

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. 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

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

SB LUCIUS,INC.
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Phone: (714) 530-2814,
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INDICATIONS FOR USE

510(K) Number : K024144

Device Name(s) : AIGIS-PT

AIGIS-PT is intended for manufacturing

- Inlay / Onlays
- Crowns
- Short span bridges
- Long span bridges
- Removable partials

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

CONCURRENCE OF CHRD,OFFICE OF DEVICE EVALUATION(OED)

Robert S Botz DDS for Dr K. Mulay
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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