SEP 17 2003

K032267

Section E 510(k) SUMMARY

Submitted by: Jensen Industries
50 Stillman Road
North Haven CT 06473
(203) 239-2090 phone
(203) 239-1015 fax
Contact: John Slanski

Date Prepared: July 18, 2003

Device Name: R&D designation AP-052-5
Common Name: Dental alloy, precious metal for porcelain-fused-to-metal
Classification: Class II
Product Code: EJT

Predicate Device(s): Helioform – K990670

Device Description:

AP-052-5 is a high-noble, gold based alloy suitable for use with the porcelain-fused-to-metal technique of fabricating dental restorations. .

Data has been presented to demonstrate that the mechanical and physical properties of AP-052-5 make it substantially equivalent to the predicate device listed, and therefore it is suitible for use as a substrate for single unit restorations in the anterior region.

Biocompatability of AP-052-5 has been assesed according to International Standard ISO 10993-1.

The safety and effectiveness of AP-052-5 is therefore determined to be equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 17 2003

Mr. John Slanski
Manager, Research & Development
Jensen Industries, Incorporated
50 Stillman Road
North Haven, Connecticut 06473

Re: K032267
Trade/Device Name: R&D Designation AP-052-5
Regulation Number: 872.3060
Regulation Name: Gold-Based Alloys and Precious Metal Alloys for Clinical use
Regulatory Class: II
Product Code: EJT
Dated: July 21, 2003
Received: August 5, 2003

Dear Mr. Slanski:

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

Indications for Use Statement

Ver/ 3 - 4/24/96

Applicant: Jensen Industries Incorporated

510(k) Number (if known): _____

Device Name: R&D designation AP-052-5

Indications For Use:

AP-052-5 is a high-noble, gold based alloy suitable for use with the porcelain-fused-to-metal technique of fabricating dental restorations. The mechanical and physical properties make AP-052-5 suitable for use as a substrate for single unit restorations in the anterior region (Bicuspids, cuspids, and incisors)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

Kevin Mulloy for MSR

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

510(k) Number: K032267