AUG 2 9 2002

Section E 510(k) SUMMARY

K022206

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

Date Prepared: June 25, 2002

Device Name: Jensen Gold Foil
Common Name: Direct filling gold foil
Classification: Class II
Product Code: EJT

Predicate Device(s): EZ Gold – K915626
Williams Gold Foil (pre-amendment device)

Device Description:

Jensen Gold Foil is pure gold, direct filling gold foil suitable for use by dentists in filling Class I, Class V, Class VI, and Pit dental preparations. Indications for use and chemical composition are identical to those of the predicate devices.

There are no standards for direct filling gold foil. The safety and effectiveness of Jensen Gold Foil is based upon the centuries long clinical success of direct filling gold foil. Gold foil is the reference standard for biocompatibility and longevity. In the hands of a skilled operator, "there can be no doubt that a properly inserted direct gold restoration is unsurpassed from the standpoint of service."[1]

[1]Phillips R.W. Skinner's Science of Dental Materials. 8th ed. Philadelphia: WB Saunders, 1982:366.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 9 2002

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

Re: K022206
Trade/Device Name: Jensen Gold Foil
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: June 25, 2002
Received: July 05, 2002

Dear Mr. Slanksi:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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). 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,

Timothy A. Ulatowski
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): K022206

Device Name: Jensen Gold Foil

Indications For Use:

Jensen Gold Foil is pure gold direct filling gold foil suitible for use by dentists in filling Class I, Class V, Class VI, and Pit dental preparations.

(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)

Susan Runner

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

510(k) Number: K022206