



AUG 25 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Star Refining Precious Metals South Africa
C/O Mr. Ned E. Devine
Responsible Third Party Official
Entela, Incorporated Engineering and Testing Laboratories
3033 Madison Avenue, SE
Grand Rapids, Michigan 49548

Re: K032106
Trade/Device Name: StarBond Dental Bonding Alloys
Regulation Number: 872.3060
Regulation Name: Gold-Basted Alloys and precious Metal Alloys for Clinicial Use
Regulatory Class: II
Product Code: EJT, EJS
Dated: August 8, 2003
Received: August 11, 2003

Dear Mr. Devine:

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 (if known):

Device Name: Starbond Dental Alloys

Classification Panel: 872.3060 EJT

Indications for Use:

STARBOND 515G

Porcelain to precious metal alloy suitable for single units, short and long span bridges for metal ceramics, as well as milled work and implant over structures.

STARBOND 525G

Porcelain to precious metal alloy suitable for single units, short and long span bridges for metal ceramics, as well as milled work and implant over structures.

STARBOND 575P

Porcelain to precious metal alloy suitable for single units, short and long span bridges for metal ceramics, as well as milled work, bars and attachments and cast partial dentures.

STARBOND 650SF

Porcelain to precious metal alloy suitable for single units, short and long span bridges for metal ceramics, as well as implant over structures.

STARBOND 780G

Porcelain to precious metal alloy suitable for a wide range of applications including: single units, short and long span bridges for metal ceramics and milled work and implant over structures.

STARBOND 860G

Porcelain to precious metal alloy suitable for single surface and multi-surface inlays, crowns, small and long span bridges as well as crown and bridge frames for metal ceramics

STARBOND 990G

Porcelain to precious metal alloy suitable for low stress situations only, single anterior, single units with full porcelain coverage.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____

or

Over the Counter Use _____



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

510(k) Number: K032106

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