K051931

FEB 17 2006

TDi
BRINGING INNOVATION

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Contact Person:	Linda Nguyen Tri Dental Innovators
Address:	13902 West Street Unit C Garden Grove, CA 92843
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Date Prepared:	July 2005
Trade Name:	AXIOM
Common Name:	Dental Restorative Composite
Classification Name:	Tooth Shade Resin Material (per 21 CFR § 872.3690)
Predicate Devices:	3M Z100 Restorative (K920425) Kerr Corporation Prodigy 4 (K990898)

Device Description

AXIOM is a light-cured hybrid dental restorative composite material, comprised of a Bis-GMA based resin, barium glass filler and fumed silica, suitable for dental filings. The cured product has a high surface luster, high strength and good wear resistance.

Intended Use

The intended use of AXIOM is for all classes of cavities.

Substantial Equivalence

All components of AXIOM are found in legally marketed predicate devices, which share similar technological characteristics that are based on monomer chemistry. This is further validated by the comparative bench test conducted; diametral strength, flexural strength, Young's modulus, shrinkage, and hardness. AXIOM has been tested for cytotoxicity and mutagenicity and were found to be non-cytotoxic and non-mutagenic.

Based on the components in AXIOM, the prior use of the same components in legally marketed predicate devices and on performance data, we believe AXIOM is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 17 2006

Ms. Linda Nguyen
Regulatory Affairs
Tri Dental Innovators
13902 West Street, Unit C
Garden Grove, California 92843

Re: K051931
Trade/Device Name: AXIOM
Regulation Number: 872.3670
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: EBF
Dated: February 6, 2006
Received: February 7, 2006

Dear Ms. Nguyen:

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.

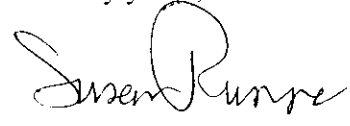
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
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): K051931

Device Name: AXIOM

Indications For Use:

- For direct restorations, for use in all classes of cavities, including veneers and incisal edge repairs.

- For indirect anterior and posterior restorations, including inlays, onlays, and veneers.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

K051931