K034024

MAR 19 2004

Section 5

510 (k) SUMMARY

1. **Applicant:** Bisco, Inc
1100 West Irving Park Road
Schaumburg, IL 60193

Contact Person: Benjamin Lichtenwalner
Ph. 847-534-6146
Fax 847-534-6111

Prepared Date: December 23, 2003

2. **Device Trade Name:** **TESCERA Fiber Bundles, Fiber Mesh, and Fiber Cylinders**
Common/Usual Name: Fiber Reinforcement material
Classification/Name: **Class II per 21 CFR 872.3760** Denture Relining, Repairing, or Rebasing Resin

3. **Predicate Device**: Ribbond-Triaxial from Ribbond, Inc, cleared under K013881 dated 01/25/2002

4. **Description of Application Device:**
TESCERA Fiber Bundles, Fiber Mesh, and Fiber Cylinders are glass fiber reinforcement materials for composite and acrylic dental restorative materials. The **TESCERA Fiber Bundles** are loose fiber bundles. The **TESCERA Fiber Mesh** is a plain woven mesh. The **TESCERA Fiber Cylinders** are woven cylinders (sleeves) that come in several diameters. They are designed to be used with the **TESCERA** indirect composite system but should be effective with other indirect and direct systems

5. **Intended Uses of Applicant Device:**
TESCERA Fiber Bundles, Fiber Mesh, and Fiber Cylinders are designed to be incorporated into devices as reinforcement in clinical situations where added strength is suggested or required. These situations include removable prosthetic devices such as dentures, splints, and orthodontic appliances as well as fixed prosthetic devices such as inlays, crowns, bridges, and splints. The intended uses of the applicant device are the same as the predicate device.

6. **Technological Characteristics:**

Technological Characteristics	TESCERA Fiber Bundles, Fiber Mesh, and Fiber Cylinders	Ribbond-Triaxial
Intended use	Reinforcing Material	Reinforcing Material
Form	Fiber bundles, woven fiber mesh and woven fiber cylinders	Woven fiber ribbon
Physical/Mechanical Properties	Increases the Flexural Strength of dental materials	Increases the Flexural Strength of dental materials

Side by side comparisons of **TESCERA Fiber Bundles, Fiber Mesh, and Fiber Cylinders** to the predicate device **Ribbond-Triaxial** from Ribbond, Inc clearly demonstrates that the applicant devices are substantially equivalent to the legally marked devices. **TESCERA Fiber Bundles, Fiber Mesh, and Fiber Cylinders** were tested for biocompatibility and they were found to be non-toxic. It is concluded that the information supplied in this submission has proven the safety and efficacy of **TESCERA Fiber Bundles, Fiber Mesh, and Fiber Cylinders**.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 2004

Mr. Benjamin Lichtenwalner
Regulatory Affairs Coordinator
Bisco, Incorporated
1100 West Irving Park Road
Schaumburg, Illinois 60193

Re: K034024
Trade/Device Name: TESCERA Fiber Bundles, Mash, and Fiber Cylinder
Regulation Number: 872.3760
Regulation Name: Denture Relining, Repairing or Rebasing Resin
Regulatory Class: II
Product Code: EBI
Dated: December 24, 2003
Received: January 7, 2004

Dear Lichtenwalner:

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) 594-5618. 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,

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): K034024

Device Name: **TESCERA Fiber Bundles, Fiber Mesh, and Fiber Cylinders**

Indications For Use:

As reinforcement for:

1. Removable dentures
2. Crown and bridge (Composite)
    a. single units
    b. multiple unit bridges
    c. inlay bridges
    d. Maryland Bridges
3. Provisional Crown and Bridge
    a. single units
    b. inlay bridges
    c. multiple unit bridges
    d. Maryland Bridges
4. Splint device reinforcement (Bruxism Appliance)
5. Splinting of teeth
6. Orthodontic Appliances

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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

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

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