

SEP 15 1998

K982729

510(k) Submission for RENEW™
BISCO, INC., 1100 W. Irving Park Road
Schaumburg, IL 60193

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510(k) SUMMARY

As Required by 21 CFR 807.93

APPLICANT DEVICE

Trade Name: RENEW™

Common Name: Composite Restorative Material

Classification Name: Tooth Shade Resin Material, Class II, 21 CFR 872.3690

LEGALLY MARKETED PREDICATE DEVICE: AELITEFIL™

PREDICATE DEVICE

AELITEFIL

AELITEFIL, universal hybrid composite, is a highly filled (75% by wt.), light cured hybrid composite restorative material. The material is radiopaque and indicated for all types of cavity preparations. The hybrid blend of ultra fine primary filler (averaging 0.7 μm with tightly controlled distribution) and submicron silica results in superior optical qualities and physical/mechanical properties. The material bonds micromechanically and chemically to dental primers/bonding resin adhesives through co-polymerization of the former's air inhibited layer. AELITEFIL is designed to be marketed as a stand alone product.

DESCRIPTION OF APPLICANT DEVICE

RENEW

RENEW, universal hybrid composite, is a highly filled (74% w/w), light-cured radiopaque hybrid composite. Its physical/mechanical properties are similar to the predicate device and uses are identical. Like the predicate device, RENEW is barium glass and silica filled dimethacrylate composite. It hardens by light cure polymerization mechanism employing light activated initiators. Both devices are designed to be used with high quality dentin/ enamel adhesive systems.

INTENDED USES OF APPLICANT DEVICE

RENEW

RENEW is indicated for: Class I, II, III, IV, V and VI restorations, direct aesthetic veneers for masking stains and developmental anomalies, core build ups to replace missing tooth structure and composite/ porcelain repairs.

510(k) SUMMARY (cont.)

SCIENTIFIC CONCEPTS and SIGNIFICANT PERFORMANCE CHARACTERISTICS

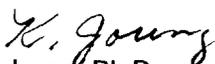
AELITEFIL and RENEW are very similar with regard to chemical composition and selected physical/mechanical properties. Significantly, AELITEFIL and RENEW have been designed to achieve 'Non-Sticky' handling before cured as well as high polishability and strength when cured. These properties are desired of resin based restoratives to be indicated for all types of cavity preparations. The hybrid blend of ultra fine primary filler (averaging 0.7 μm with tightly controlled distribution) barium glass, and silica results in high strength and polishability of cured AELITEFIL and RENEW. The Bis-GMA and UDMA monomers of AELITEFIL are balanced to achieve 'Non-Sticky' handling. RENEW is based on the the ethoxylated version of Bis-GMA resulting in reduction of 'stickiness' even more.

The chemical compositions of AELITEFIL and RENEW are quite similar. Both are barium glass and silica filled methacrylate hybrid composites. Both are light cured, and radiopaque for easy radiographic identification and evaluation.

The non-clinical tests used for this submission are similar to those specified in ISO 4049 and American Dental Association Specification #27; both are for dental resin based filling materials. Diametral tensile testing (DTS) is an accepted method to characterize the tensile strength of brittle materials and the flexural modulus test addresses the strength in three point loading. DTS values are 45 and 50 MPa for AELITEFIL and RENEW respectively.

Biocompatibility of RENEW, Cytotoxicity, was tested in conformance with good laboratory practice and EN 45001 (ISO 10993-5) by a commercial testing laboratory (NAMSA) and the product was found to be non-toxic.

Side by side comparisons of RENEW to the predicate device provided in this submission clearly demonstrated that the applicant device, RENEW, is substantially equivalent to the legally marketed predicate device, AELITEFIL, in terms of effectiveness or suitability to the intended uses.


Kathy Joung, Ph.D.
QA/QC Manager
1-800-BIS-DENT or 847-534-6106
Fax: 847-891-6865
August 3, 1998

REFERENCES

1. Craig, R. G. (ed), Restorative Dental Materials, eighth edition, C. V. Mosby Co., St. Louis, 1989, p 277.
2. International Standards Organization, ISO 4049:1988/Cor. 1:1992 (E), Resin Based Filling Materials, 1992.
3. Bisco, Inc. Quality Control Testing Procedure, QC-0004, 1987.
4. *ibid.* QC-003, 1998
5. *ibid.* QC-006, 1997



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 15 1998

Kathy Joung, Ph.D.
QA/QC Manager
BISCO, Incorporated
1100 W. Irving Park Road
Schaumburg, Illinois 60193

Re: K982729
Trade Name: RENEW™
Regulatory Class: II
Product Code: EBF
Dated: August 3, 1998
Received: August 5, 1998

Dear Dr. Joung:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

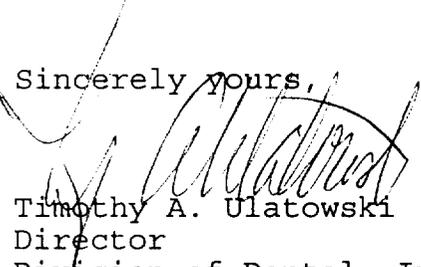
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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 Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K982729

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INDICATIONS for USE

510(k) Number (if known): -- K982729

Device Name: RENEW™

Indications for Use:

1. Class I, II, III, IV, V and VI restorations.
2. Direct aesthetic veneers for masking stains and developmental anomalies.
3. Core build ups to replace missing tooth structure.
4. Composite and porcelain repairs.

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

Concurrence of CDRL, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

Susan Pardo

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

510(k) Number K982729