

DEC 22 1998

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

33 of 36

KAS 4112

SUMMARY

Legally Marketed Predicate Device belleGlas™ HP

The belleGlas™ HP system includes a Dentin and Enamel component. The Dentin component is engineered for high physical and mechanical strength and the Enamel component is formulated for high resistance to wear and abrasion. Both components are highly filled, radiopaque composites designed for indirect restorations. The belleGlas™ HP composites are cured by light, heat, and pressure in a dedicated device.

Description of Applicant Device ADVENT™

The ADVENT™ system is also comprised of a Dentin component and an Enamel component. ADVENT Dentin is a highly filled (78.6% w/w) composite designed for class I, II, III, IV, V, and VI restorations and composite core build-up. ADVENT™ Enamel is a highly filled composite which, like belleGlas™ Enamel, is designed for high resistance to wear and abrasion as well as good polishability. Both Dentin and Enamel components are radiopaque and polymerizable by a dual cure system (heat/light), i.e., can be light cured by conventional means or processed in a dedicated curing device that employs heat and light in a pressurized, oxygen-free nitrogen atmosphere. The ADVENT™ system is designed to be used with high quality dentin/enamel adhesive systems.

Intended Uses of Applicant Device ADVENT™

ADVENT™ is intended for direct or indirect class I, II, III, IV, V, and VI restorations and composite core build-up. ADVENT™ is also intended for composite restorations bonded to tooth structure, metal, composite, fiber-reinforced substructure, and porcelain.

Scientific Concepts and Significant Performance Characteristics

The ADVENT™ and belleGlas™ HP systems are very similar with regard to chemical composition and selected physical/mechanical properties. Significantly, belleGlas™ HP and ADVENT™, following curing, have been designed to have increased wear resistance, tensile strength, and compressive strength. These properties are essential to a composite in order for it to function effectively. The highly viscous nature of belleGlas™ HP and ADVENT™ allows them to be easily sculpted and shaped.

The chemical compositions of belleGlas™ HP and ADVENT™ are quite similar. Both are silica and glass filled dimethacrylate hybrid composites. Both can be cured by heat, light, and pressure in dedicated devices.

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 strength (DTS) is an accepted method to characterize the tensile strength of brittle materials. DTS of ADVENT™ Dentin and belleGlas™ Dentin are, respectively, 65 and 63 MPa. DTS of ADVENT™ Enamel and belleGlas™ Enamel are, respectively, 55 and 57 MPa.

Biocompatibility of ADVENT™, cytotoxicity, was performed per ISO 10993-5 by a commercial testing laboratory (NAMSA) and the product was found to be non-toxic.

Comparison of ADVENT™ to the predicate device illustrates that the two items are very similar. The major difference between the two systems is in the intended uses. ADVENT™ may be used for direct as well as indirect restorations. The predicate device is designed specifically for direct restorations only.

Steven J. Duray, Ph.D.
Manager of Technical Business Support Services
1-800-BIS-DENT or (847) 534-6094
FAX: (847) 891-6705
November 16, 1998

REFERENCES

1. International Standards Organization, ISO 4049:1988/Cor. 1:1992 (E), Resin Based Filling Materials, 1992.
2. BISCO, INC. Quality Control Procedures, QC-0003, 1987.
3. *ibid.* QC-0004.
4. *ibid.* QC-0006.
5. Craig, R. G (ed.), Restorative Dental Materials, eighth edition, C. V. Mosby Co., St. Louis, 1989, p 277.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 1998

Steven J. Duray, Ph.D.
Manager of Technical Business Support Services
BISCO, Incorporated
1100 W. Irving Park Road
Schaumburg, Illinois 60193

Re: K984112
Trade Name: ADVENT™
Regulatory Class: II
Product Code: EBF
Dated: November 16, 1998
Received: November 17, 1998

Dear Dr. Duray:

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 (Premarket 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

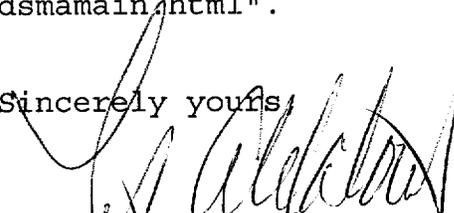
Page 2 - Dr. Duray

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

INDICATIONS FOR USE

510(k) Number (if known): K984112

Device Name: ADVENT™

Indications for Use:

1. Direct or indirect class I, II, III, IV, V, and VI restorations.
2. Core build-up material to replace missing tooth structure.
3. Composite restorations bonded to tooth structure.
4. Composite restorations bonded to metal.
5. Composite restorations bonded to composite or fiber-reinforced substructure.
6. Composite restorations bonded to porcelain.

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

Concurrence of CDRL, Office of Device Evaluation (ODE)

Prescription for Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

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

510(k) Number K984112