K974483 Feb 9, 1998

510(k) SUMMARY
As Required by the Safe Medical Devices Act of 1990

IDENTIFICATION OF THE LEGALLY MARKETED PREDICATE DEVICE

PREDICATE DEVICE
AELITEFLO™

AELITEFLO is a low viscosity, light-cure hybrid composite restorative material. It is a moderately filled (59% w/w), radiopaque, flowable composite designed primarily for restoration of shallow defects such as incipient Class V lesions. It functions well as an anterior esthetic material to re-shape and esthetically restore stained or otherwise developmentally compromised anterior teeth. AELITEFLO bonds micromechanically and chemically to dental primers/bonding resin adhesives through co-polymerization of the former's air inhibited layer. AELITEFLO is designed to be marketed as a stand alone product but can be made available in kit form including semi-gel etchant [K945604] and COMPOSITE PRIMER.

DESCRIPTION OF APPLICANT DEVICE
NTL-FLOW

NTL-FLOW is a dual-cure (light or heat and light) moderately filled (60%), radiopaque low modulus flowable composite. Its physical properties are similar to the predicate device and uses are identical. Like the predicate device, NTL-FLOW is a glass frit filled dimethacrylate composite. It hardens by a light or heat and light cure polymerization mechanism employing a light initiator, and a tertiary amine activator and peroxide initiator. Both devices are designed to be used with high quality dentin / enamel adhesive systems. The material can be used in a conventional fashion or it can be processed in a dedicated curing device that employs light, and a substantially oxygen free atmosphere created by flushing the device with an inert gas such as nitrogen. The heat is supplied by the lamp providing the light. The comparative low modulus facilitates the use of the material as a first increment liner that is intended to bond to the dental adhesive as well as the next increment composite.

INTENDED USES OF APPLICANT DEVICE
NTL-FLOW

NTL-FLOW is indicated for: anterior esthetic restorative material for Class III and IV as well as conservative Class I restorations not involving opposing occlusal wear, direct esthetic veneer restorative for masking stains and developmental anomalies, pit and fissure sealant, core build-up material to replace missing tooth structure, dental cement/luting agent, composite repair, and a liner/base material.

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SCIENTIFIC CONCEPTS and SIGNIFICANT PERFORMANCE CHARACTERISTICS

AELITEFLO and Bisco NTL-FLOW are very similar with regard to chemical composition and selected physical/mechanical properties. Significantly, AELITEFLO and NTL-FLOW, following curing, have been designed to be more flexible than conventional dental composites. Also, the flow characteristics or so-called syringability of these materials are superior to more highly filled materials. The viscoelastic properties of conventional microfil composites are dependent on the interaction of submicron silica fillers and the design resin. Because of the enormous surface area of submicron silica, a much smaller amount of filler can be incorporated into a composite compared with a larger filler such as 0.7μm barium glass as used in NTL-FLOW and AELITEFLO. The flowability of NTL-FLOW, therefore, is achieved by a careful balance of resin viscosities and filler loading. Submicron filler is also used in NTL-FLOW but to a much lesser extent than conventional microfil composites.

The flexibility of cured NTL-FLOW is achieved by an imaginative balance of polymerizable resins. These resins in concert with the fillers noted above achieve the properties described in this application, namely high service strength, flexibility, and ease of manipulation or syringability. Relative reduction of filler content typically reduces surface hardness of composites and that is evident with NTL-FLOW which has approximately 10% lower Barcol hardness than conventional composites.

The chemical composition of NTL-FLOW and AELITEFLO are quite similar. Both are silica and /or glass filled dimethacrylate light-cure composites. NTL-FLOW is based on the ethoxylated version of Bis-GMA whereas AELITEFLO is primarily a Bis-GMA triethyleneglycol dimethacrylate combination.

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 41.3 and 39.0 MPa for NTL-FLOW and AELITEFLO respectively. Cytotoxicity of NTL-FLOW was performed by a commercial testing laboratory (NAMSA) and the product was found to be non-toxic.

Comparison of NTL-FLOW to the predicate device shows both are very similar with the major difference being the methods of final cure of the product. The proposed new product cures using visible light or heat (125°C) and light. The predicate device can cures using visible light exclusively.

James L. Sandrik

James L. Sandrik, Ph.D.
BISCO, Inc.
Schaumburg, IL 60193
November 25, 1997

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 9 1998

James L. Sandrik, Ph.D.
Director of Technical Affairs
Bisco, Incorporated
1100 West Irving Park Road
Schaumburg, Illinois 60193

Re: K974483
Trade Name: NTL-FLOW™
Regulatory Class: II
Product Code: EBF
Dated: November 25, 1997
Received: November 26, 1997

Dear Dr. Dandrik:

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 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 requirement, 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) 594-4618. 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" (21 CFR 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/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): K974483

Device Name: NTL-FLOW

Indications for Use:

1. Anterior esthetic restorative material for Class III, IV, and V as well as conservative Class I restorations not involving opposing occlusal wear for direct or indirect use.
2. Direct Esthetic veneer restorative for masking stains and developmental anomalies.
3. Pit and fissure sealant.
4. core build-up material to replace missing tooth structure.
5. Dental cement/luting agent and dental liner.
6. Composite/porcelain repair material.

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

Concurrence of CDRL, Office of Device Evaluation (ODE)

Infection Control,
Hospital Devices

510(k) Number K974483

Prescription Use X OR Over-The-Counter Use NA
(Per 21 CFR 801.109)

(Optional Format 1-2-96)