K012354

OCT 1 0 2001

510(k) Summary
(As Required by 21 C.F.R. §807.92)

Submitted by: Craig Bruns
Vice President
Danville Materials, Inc.
2021 Omega Dr.
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Date of summary: July 20, 2001

Device name: Snowpost & Snowlight

Common name: Glass fiber composite root canal post

Classification names:

Regulation Number	Classification Name
972.3810	Dental root canal post

Predicate Device: The modified device is substantially equivalent to the previously cleared Bisco UM Aesthetic Post (K945370), Coltene ParaPost Fiber White (K000311), Jeneric/Pentron FibreKor Post (K983266), and Harald Nordin Glassix post (K003221) devices.

Modifications: The primary differences are minor changes to the material and dimensions.

Intended Use: The modified device has the same intended use as the legally marketed predicate devices herein referenced. The Snowpost & Snowlight composite posts are intended for use by dentists to give retention for reconstruction of non-vital teeth.

Technological Characteristics: The modified device has the same technological characteristics as the legally marketed predicate device mechanically supporting reconstruction.

Testing: ISO 10993-5 "Biological evaluation of medical devices - Tests for Cytotoxicity: in vitro methods" was conducted and shows no evidence of a cytotoxic response. Mechanical tests were conducted in conformance with ISO 3597-2-94 Three-point Bending Standard results showed the material to be suitable for root canal posts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 0 2001

Mr. Craig R. Bruns
Vice President
Danville Materials, Incorporated
2021 Omega Drive
San Ramon, California 94583

Re: K012354
Trade/Device Name: Snowpost & Snowlight
Regulation Number: 872.3810
Regulation Name: Root Canal Post
Regulatory Class: I
Product Code: ELR
Dated: July 18, 2001
Received: July 25, 2001

Dear Mr. Bruns:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K012354

Device Name: Snowpost & Snowlight

Indications for use:

Snowpost & Snowlight posts are indicated for use wherever root canal posts are required and where esthetic considerations and/or where known metal allergies are of concern.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012354