K973976

510(k) SUMMARY

DEC - 4 1997

Submitter:

Parkell Products Inc.
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Contact:

Nelson J. Gendusa, DDS
Director of Research
Parkell
155 Schmitt Blvd.
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Farmingdale, NY 11735

Submission Date: 17 October 1997

Trade Name: EPIC-FLO

Common Name: Flowable Composite Resin

Classification Name: Tooth Shade Resin Material (C.F.R. §872.3690)

Equivalence: Zenith Flowable Composite, Centrix Flo-Fil, Aeliteflo, Ultradent Flowable Composite, Comp=Flow, et. al.

Description/Intended Use: EPIC-FLO is a light-cured, flowable composite, for use as a tooth restorative in all class cavities (I, II, III, IV and V). It is especially suitable for use in non-stress bearing class I and III restorations and for class V lesions. It may be used as a liner in all class cavity preparations, and as a pit and fissure sealant or as a composite luting resin. The material is well-suited as an undercut block-out material in cavity preparations. It may be used with all currently available dentin bonding systems. EPIC-FLO is substantially equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Nelson J. Gendusa, DDS
Director of Research
Parkell Products, Incorporated
155 Schmitt Boulevard
Farmingdale, New York 11735

DEC - 4 1997

Re: K973976
Trade Name: EPIC-FLO
Regulatory Class: II
Product Code: EBF
Dated: October 16, 1997
Received: October 20, 1997

Dear Dr. Gendusa:

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

510(k) Number (if known): K 973976

Device Name: Epic -Flo

Indications For Use:

A light-cured, flowable composite, for use as a tooth restorative in all class cavities (I, II, III, IV and V). It is especially suitable for use in non-stress bearing class I and III restorations and for class V lesions. It may be used as a liner in all class cavity preparations, and as a pit and fissure sealant or as a composite luting resin. The material is well-suited as an undercut block-out material in cavity preparations. It may be used with all currently available dentin bonding systems.

(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 Dental, Infection Control,
and General Hospital Devices
510(k) Number K973976

Prescription Use Yes
(Per 21 CFR 801.109)

OR

Over-The-Counter Use No

(Optional Format 1-2-96)