

The recently 510(k) cleared composite restorative material REFERENCE[®] will be marketed under the tradename PROMPTFIL[®]. However, in this Special 510(k) submission the name REFERENCE[®] is used to avoid misunderstanding and confusion.

ESPE is submitting this Special 510(k) for modifications of its composite based restorative material REFERENCE[®]. The modification results in PROMPTFLOW[®], a flowable composite restorative material. PROMPTFLOW[®] has the same fundamental scientific technology and the same intended use as REFERENCE[®], therefore, we believe these modifications are eligible for the Special 510(k) process.

To achieve the flowability of PROMPTFLOW[®] the filler content had to be reduced. As a result, some mechanical strength characteristics decreased which leads to a reduced range of indications. However, comparison with another flowable restorative material, DYRACT[®] FLOW by Dentsply, shows, that PROMPTFLOW[®] is a suitable material for the claimed indications for use.

In this Special 510(k) Device Modification submission the chemical composition, the physical and mechanical properties, and the indications for use of both the unmodified REFERENCE[®] and the modified PROMPTFLOW[®] are compared. Furthermore, ESPE's design control activities are shortly described. DYRACT[®] FLOW is provided to have a predicate flowable restorative material because, as described above, the physical and mechanical properties of PROMPTFLOW[®] are not as strong as those of REFERENCE[®] due to the lower filler content.

However, the modified restorative material PROMPTFLOW[®] has the following similarities to the unmodified REFERENCE[®]:

- PROMPTFLOW[®] has in general the same intended use
- PROMPTFLOW[®] is used by the same operating principle
- PROMPTFLOW[®] incorporates the same basic chemical design
- PROMPTFLOW[®] has the same shelf life
- PROMPTFLOW[®] is manufactured using the same materials and processes

In summary PROMPTFLOW[®] described in this submission is, in our opinion, substantially equivalent to the predicate devices.



DEC - 6 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Andreas Petermann
Manager U.S. Regulatory Affairs
ESPE Dental AG
ESPE Platz
D2229 Seefeld, Bavaria

Re: K993566
Trade Name: Promptflow®
Regulatory Class: II
Product Code: EBF
Dated: October 28, 1999
Received: November 1, 1999

Dear Mr. Petermann:

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.

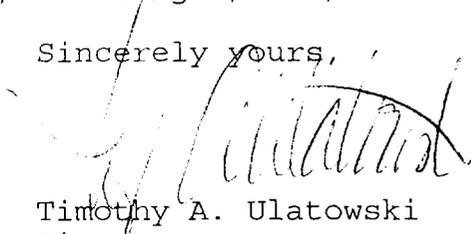
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 pre-market 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" (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

K993566

STATEMENT OF INDICATIONS FOR USE

(As Required by 21 C.F.R. § 801.109)

510(k) Number: K993566

Device Name: PROMPTFLOW®

Indications for use: Flowable composite restorative material for:
Minimally-invasive fillings
Restorations of type III and V cavities (according to Black)
Liner for restorations of type I and II cavities
Small restorations of type I and II cavities
Deciduous tooth fillings
Fissure sealing
Extended fissure sealing
Tunnel preparation
Repair of composite fillings and ceramic veneers
Filling of defects and undercuts in crowns, inlays, and onlays
Cementing porcelain veneers, crowns, inlays, and onlays
Refacing acrylic temporaries
Blockouts

Prescription use: Sugar Runoe Over-the counter use

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K993566