

510(k) SUMMARY

K 992489

JAN 11 2000

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

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Regulatory Affairs Specialist
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Telephone: 612-733-3594
Fax: 612-736-0990
Trade Name: 3M™ TR System
Common Names: Porcelain mill block material, Alumina core material
Classification Name: 21 CFR § 872.6660 Porcelain powder for clinical use, Class II

Predicate Devices: Vitabloc Mark II and In-Ceram Alumina both made by Vident

3M™ TR System is a ceramic material. It is intended to be used by dental laboratories and dentists (with chair side dental milling units) to create specific restorations.

The 3M™ TR System is indicated for copings and frameworks for inlay, onlay, veneer, crown and anterior bridge restorations. 3M™ TR System is not indicated as an implant material. The 3M™ TR System is not recommended for bruxers or clenchers.

3M™ TR System and predicate devices have similar technological characteristics. This has been validated by the comparing results of published laboratory data, along with 3M generated bench data. These tests include compressive strength, fracture toughness and flexural strength.

Based on the conclusions drawn from the safety information available on this material, past history with it's use, the results of the bench testing and published literature, the 3M™ TR System is safe, effective and performs as well or better than the predicate devices mentioned above.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 11 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Lael J. Pickett
Regulatory Affairs Specialist
3M Center
St. Paul, MN 55144-1000

Re: K992489
Trade Name: 3M™ TR System
Regulatory Class: II
Product Code: EIH
Dated: July 16, 1999
Received: July 26, 1999

Dear Mr. Pickett:

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 premarket notification submission does not affect any

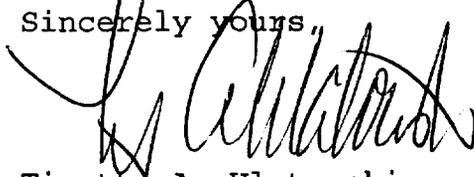
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obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

510(k) Number (if known): _____

Device Name: 3M™ TR System System

Indications For Use: This device is indicated for:

- Fabricating copings and frameworks for inlays, onlays, veneers, crowns and anterior bridge restorations

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____



(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number 1092489