

FEB 4 1999

10. 510(k) Summary or Statement**SUMMARY**

K984037

Gentleman:

This submission is pursuant to paragraph 510(k) of the Federal Drug and Cosmetic Act of May, 1976 (as amended) (Title 21 USC). All informations contained herein are to be considered and treated as CONFIDENTIAL COMMERCIAL INFORMATION.

It is the intention of P. L. Superior GmbH to distribute the Roydent DC-Core / Core-Ide cited above manufactured at its facilities at Robert-Bosch-Str. 5, D-25335 Elmshorn, which can be used as Core Build Up material.

P. L. Superior GmbH specializes in distributing and marketing numerous dental materials and related items manufactured at its facilities at Robert-Bosch-Str. 5, D-25335 Elmshorn, worldwide.

It is P. L. Superior GmbH's intention to distribute DC-Core / Core-Ide cited herein which is manufactured at its facility located at Robert-Bosch-Straße 5, D-25335 Elmshorn, Germany, employing Good Manufacturing Practices (GMP's) pursuant and according to Title 21 CFR. P. L. Superior GmbH is certified to DIN EN ISO 9003 / DIN EN 46003 and Medical Device Directive (MDD) 93/42/EEC, annex VI.

The DC-Core / Core-Ide may be offered and marketed in the United States by Roydent, in which case P. L. Superior GmbH will maintain control and govern the production and primary packaging. Roydent will maintain the claims, labels, instructions and indications by himself which are consistent with this submission and final FDA 510(k) clearance to market by P. L. Superior GmbH.

The chemistry of DC-Core / Core-Ide P. L. Superior GmbH distributes for Roydent is commonly used in current dental materials.

The purpose of this material for use by the dentist is to clinically build up human teeth (restoration in the case of mostly destroyed tooth structure). The material is in general placed against an applied adhesive system.

The chemical composition and use of DC-Core / Core-Ide is substantially equivalent to "BIS-CORE Core Build Up Composite", a product manufactured and marketed by BISCO Dental Products, ITASCA, ILLINOIS USA.

Respectfully submitted

Jürgen Engelbrecht, Ph. D.
Regulatory Compliance Officer



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 4 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Don Leroy
President
ROYDENT Dental Products
1010 West Hamlin Road
Rochester Hills, Michigan 48309

Re: K984037
Trade Name: Core-Ide
Regulatory Class: II
Product Code: EBD
Dated: September 1, 1998
Received: November 12, 1998

Dear Mr. Leroy:

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.

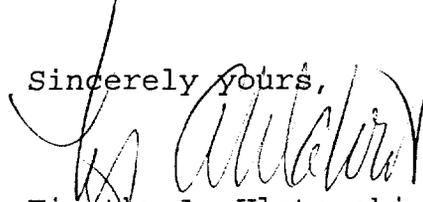
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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

9. Statement of Indications for Use

510(k) Number (if known): -

Device Name: DC-Core / Core-Ide

Indications for Use:

DC-Core / Core-Ide is a self cure micro hybride composite for endodontic post cementations and core build-ups (see enclosed Instruction for Use, MSDS).

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use:

or

Over-The-Counter Use:

Susan Rimmer

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number 7C 101037