DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. H.J. Vogelstein
Official Correspondent
Colténe/Whaledent Incorporated
750 Corporate Drive
Mahwah, New Jersey 07430

MAR - 9 1998

Re: K974465
Trade Name: Synergy
Regulatory Class: II
Product Code: EBF
Dated: February 12, 1998
Received: February 13, 1998

Dear Mr. Vogelstein:

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): K974465

Device Name: SYNERGY Composite System

coltène whaledent

Coltène/Whaledent Inc.
750 Corporate Drive
Mahwah, NJ 07430
Telephone: 201-512-8000

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SYNERGY 510(k) Submission
SYNERGY Composite System
Indications For Use

SYNERGY Shades (enamel) A1/D2, A2/B2, A3/D3, A4/M5, A3.5/B3, C2/C3 is indicated for:
- direct filling of class I, II, III, IV and V cavities
- reconstruction of natural enamel and dentine
- reconstruction of fractured anteriors
- sealing of extended fissure in molars and premolars
- stabilization of mobile anteriors
- repair of veneer facings
- fixation of splints
- bonded bridges
- esthetic

Synergy Compact (dentin) A2/B2, A3/D3, A3.5/B3 is specifically indicated for:
- core reconstruction in highly esthetic class I, II, III restorations, which are subsequently covered with a more translucent material
- direct class V fillings
- direct filling of opaque teeth
- palatinal of class IV restorations
- core build-ups
- shape and color corrections to improve esthetics

SYNERGY Transparent is specifically indicated for:
- reconstruction of incisal edges in class IV fillings
- translucent surface layers in all classes
- covering characterizations

Super White is especially indicated for:
- restoration of whitened teeth
- restoration of deciduous teeth
- characterization of chalk spots
- veneering of anteriors

Contra-indications:
- If allergies exist to any of the components of coltène® SE Composite.
- If the site cannot be isolated after enamel etching and during application and curing of coltène® SE Composite.
- If oral hygiene is poor.

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

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K974465

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

(Optional Format 1-2-96)