K030168

MAR 21 2003

5. 510 (k) Summary

Submitter of 510(k): Wieland Dental + Technik GmbH & Co.
Schwenninger Str. 13
D-75179 Pforzheim
Germany
Phone: +49-7231-3705-0

Contact person: Dr. Gerhard Polzer
Phone: +49–7231–3705–219
Fax: +49-7231-357959
e-mail: gerhard.polzer@wieland-dental.de

Date of Summary: 2003-01-14

Trade name: AGC®Cem

Classification name: Dental cement
Product code: EMA
C.D.R section: 872.3275
Classification: Class II

Legally marketed equivalent device: Permacem

510(k) number: K012316

Device description

AGC®Cem is a dental luting material, which can be used by dental technicians to manufacture dental restorations.

It is a two-component chemical (self)-curing compomer with a golden yellow color.

AGC®Cem is especially designed for the permanent luting of AGC® SupraCaps, i.e. pure gold caps, which had been electroformed with the AGC® Galvanoforming technique, in tertiary structures to produce removable dentures.

Possible uses of the AGC®Cem include

- luting of AGC® SupraCaps as telescopic crowns in chrome cobalt substructures
- luting of AGC® SupraCaps in implant supraconstructions.

AGC®Cem is offered in an Automix-System, that ensures automatic mixing of the two components. It generates a homogeneous material quality and allows direct application of the material.

AGC®Cem creates an excellent fit owing to its low film thickness and lead to high adhering strengths. Its golden yellow color provides an excellent basis to the dental technician to manufacture aesthetically pleasant dental restorations.

AGC®Cem fully complies to the international standard ISO 4049:2000 and fulfills the essential requirements of the European directive 93/42/ECC concerning medical devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 21 2003

Dr. Gerhard Polzer
Director, Regulatory Affairs
Wieland Dental + Technik GmbH & Co. KG
Schwenninger Strasse 13
D-75179 Pforzheim
GERMANY

Re: K030168
Trade/Device Name: AGC® Cem
Regulation Number: 21 CFR 872.3275(2)(b)
Regulation Name: Dental Cement
Regulatory Class: II
Product Codes: EMA
Dated: January 14, 2003
Received: January 17, 2003

Dear Dr. Polzer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4613. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030168

Device Name: AGC®Cem

Indications For Use:

AGC®Cem is a dental self-curing compomer cement for the permanent cementation of AGC® SupraCaps in tertiary structures such as secondary telescopic crowns in chrome cobalt substructures, or SupraCaps in implant supraconstructions.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulloy for MSR

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

510(k) Number: K030168

Prescription Use X OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)