510(k) Notification

K993556

JAN - 3 2000

510(k) Summary

Submitter

MedLogic Global Corporation
4815 List Drive, Suite 111
Colorado Springs, Colorado 80919

Contact:

Stephen J. Tamsett
Manager Regulatory Affairs and Quality Assurance

Phone: 1-800-625-6442
Fax: 1-719-535-2930

Date summary was prepared:

October 19, 1999

Name(s) of the device

LiquiBand® Dental adhesive

Identification of predicate device(s)

The predicate device for LiquiBand® Dental adhesive is OCTYLDENT® Dental Adhesive by Closure Medical Corporation

Description of the device

The LiquiBand® Dental adhesive formula consists of n-butyl cyanoacrylate monomer containing small amounts of hydroquinone (a free radical inhibitor) and sulfur dioxide (an anionic inhibitor).

LiquiBand® Dental, n-butyl cyanoacrylate adhesive, is a clear, colorless, free-flowing liquid packaged in a single use, 0.5 gram high density polyethylene ampoule with an attachable polypropylene applicator tip. It is applied as a liquid monomer to the bonding surface of the cap/crown to be cemented to a tooth. Upon seating the cap/crown and contact with weak bases LiquiBand® Dental polymerizes as to form a strong adhesive bond between the cap/crown and tooth.

Intended Use

LiquiBand® Dental n-butyl cyanoacrylate is intended for use as a permanent cementation when bonding of crown and caps to teeth is desired.

Comparison of device characteristics to predicate

LiquiBand® Dental adhesive is substantially equivalent to OCTYLDENT® Dental Adhesive. This is based on the same intended use, similar materials and similar means of application.

Nonclinical testing

LiquiBand® Dental adhesive was subjected to chemical, physical and biocompatibility testing to demonstrate its equivalence to OCTYLDENT® Dental Adhesive. All of the testing supported the substantial equivalence by the similarity of the test results. Both products are effective as dental cements. Based on this data, it was concluded that LiquiBand® Dental adhesive is substantially equivalent to OCTYLDENT® Dental Adhesive.

Conclusion

Based on the descriptive information and the performance data provided in this premarket notification, it is concluded that the LiquiBand® Dental adhesive is substantially equivalent to OCTYLDENT® Dental Adhesive by Closure Medical Corporation, a legally marketed dental adhesive.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Dr. Walter Fabisiak, Director
Product Development and Regulatory Affairs
and Quality Assurance
MedLogic Global Corporation
4815 List Drive
Colorado Springs, Colorado 80919

Re: K993556
Trade Name: Liquiband® Dental
Regulatory Class: II
Product Code: EMA
Dated: December 14, 1999
Received: December 15, 1999

Dear Mr. Fabisiak:

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 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 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

K993556

Indications for Use: LiquiBand® Dental Adhesive

LiquiBand® Dental n-butyl cyanoacrylate is intended for use as an adhesive when bonding of caps and crowns to teeth is desired.

Prescription Use ✓
(Per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K993556

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