



SEP 17 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Bernard van Duijn
Manager Technical Services
Cavex Holland BV
Harmenjansweg 19-21
P.O. Box 852
2003 RW Haarlem (Holland)

Re: K981970
Trade Name: CA 37 Superior Pink, CA 37 Fast Set, Cavex
Rainbow, Cavex Impressional Normal Setting, Cavex
Impressional Fast Setting, Algetral, Cavex Chromatic,
Alginoplast Normal Setting, Alginoplast Fast Setting;
and Xantalgin Select
Regulatory Class: II
Product Code: ELW
Dated: May 14, 1998
Received: June 4, 1998

Dear Mr. Bernard van Duijn:

This letter corrects our substantially equivalent letter of
September 2, 1998, regarding the product name.

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 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).
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 requirements, as set forth in
the Quality System Regulation (QS) for Medical Devices:
General (QS) regulation (21 CFR Part 820) and that, through
periodic QS inspections, FDA will verify such assumptions.
Failure to comply with the GMP regulation may result in
regulatory action. In addition, the Food and Drug

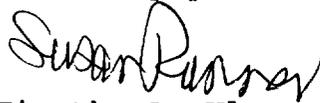
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Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 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. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


for Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) NUMBER (IF KNOWN) :

DEVICE NAME: Algetral and Cavex Chromatic
Alginate Impression Materials

INDICATIONS FOR USE:

Algetral and Cavex Chromatic are dental impression materials based on alginate. They are used for taking impressions of the oral cavity with the purpose of constructing a gypsum cast that is a copy of the situation in the mouth. They are general purpose impression materials for making study models, first impressions for the construction of individual trays, situation models, orthodontic impressions etc.

Cavex Chromatic has the special characteristic of being a color-changing alginate: it becomes violet upon contact with water in the mixing bowl, changes to pink indicating the end of the mixing time and then finally changes to off-white indicating the end of the setting time in the mouth.

(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
(Optional Format 1-2-96)

Susan Pinner
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number 12981970