

K 980018

MAY 19 1998

8. SMDA Summary of Safety and Effectiveness - "510(k) Summary"

A. Submittor Information

Newave Medical Inc.
c/o Interactive Consulting Ins.
70 Walnut Street
Wellesley, MA 02181

Telephone: 617 239-8108

Contact Person: Jean-Luc Boulnois
Secretary

Date Prepared: December 26, 1997

B. Device Identification

Common/Usual Name	Glass Strength Restorative Dental Materials
Proprietary Name:	CRISTOBAL

C. Identification of Predicate Device(s)

CRISTOBAL is substantially equivalent to the following previously cleared and currently marketing devices:

Kulzer Dentacolor (K831215)
Heraeus Kulzer ArtGlass (K954115)

D. Device Description

CRISTOBAL consists of a series of layered composite restorative glass strength materials, combining the benefit of porcelain, composite and dental alloys, whose combined properties of wear resistance, flexural strength, maximum compressive strength and bulk modulus, make it suitable for all types of fixed cosmetic prosthetic restorations. CRISTOBAL offers the patient a tooth colored occlusal surface with the feeling of natural teeth.

CRISTOBAL is subject to complete polymerization for optimal reactions of the various materials. Due to the fact that the light curing material of CRISTOBAL is radio-opaque, and its matrix has a very high content in inorganic particles (barium borosilicate), it allows for the production of fixed prostheses with functional, mechanical, and cosmetic longevity.

CRISTOBAL is composed of silanized barium borosilicate particles, a non-fracturable filler material, which are closely packed (74.2 weight percent) providing optimal silanization and cohesion of glass thereby ensuring protection against fracture together, with strong resistance to damage. With the matrix of Bis-GMA, TEDMA and UDDMA, these elastic memory properties also ensure damage resistance.

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E. Substantial Equivalence

The technical characteristics of CRISTOBAL are almost identical to those of the Heraeus Kulzer ArtGlass and the Kulzer Dentacolor. Refer to Table A for a comparison of these predicate devices. Differences that exist between these devices relating to technical specifications, materials, physical appearance, and control systems, do not affect the relative safety or effectiveness of the CRISTOBAL materials.

The Newave Medical CRISTOBAL, the Heraeus Kulzer ArtGlass, and the Kulzer Dentacolor are intended to be used for construction of cosmetic prosthetic restoratives for use in fixed restorations, with or without metal frameworks for:

- single crowns,
- telescope crowns,
- conus crowns,
- bridges, (with metal-frame)
- Maryland bridges,
- bridges on implants,
- inlays,
- onlays
- facettes (lamine veneers), and
- restorations.

TABLE A
Comparison Table: Restorative Dental Materials

<u>Manufacturer:</u>	Kulzer	Heraeus Kulzer	Newave Medical Inc.
Model	DENTACOLOR	ARTGLASS	CRISTOBAL
K-Number	K831215	K954115	
Class	II	II	Request II
<u>Properties of Strength:</u>			
Bending/Flexural (MPa)	70-75	120	155
Modulus Flexibility (MPa)	3300 - 3500	9 000	8 500
Comprehensive (MPa)	350	Not Available	350
Vickers-Hardness (N/mm ²)	400	590	670
Fracture Damage during Vickers Hardness Tests (mm ²)	Not Available	Not Available	0,245
Abrasion (µm/year)	Not Available	Good	<8
Bulk Modulus NFT 51101 (MPa)	Not Available	Not Available	4 084
Water Solubility (ug/mm ²)	1	0.5	-10 ⁻²
<u>Chemical Composition</u>			
Type of Filler Material	Pyrogenic Silicon Dioxide	Microfine Glass Particles	Barium Borosilicate
Total Mineral Filler Content by Weight (%)	51	72	77
<u>Other:</u>			
Glazing Technique	Mechanical Polishing	Mechanical Polishing	Mechanical Polishing
Polymerization Shrinkage (%)	0.16	Negligible	0.12
Shade Stability (ΔE)	~3	2	High

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Manufacturer:

**Kulzer
DENTACOLOR**

**Heraeus Kulzer
ARTGLASS**

**Newave Medical Inc.
CRISTOBAL**

Clinicals:

**Clinical Claims
With or Without Metal-Frames**

**Crowns
Bridges**

**Veneers
Inlays
Onlays
Crowns
Bridges
Maryland Bridges
Implant Supported Restorations
Telescope and Conus Crowns
Attachment retained prosthesis**

**Single Crowns
Telescope Crowns
Conus Crowns
Bridges (with metal-frame)
Maryland Bridges,
Bridges on Implants
Inlays
Onlays
Facettes (Laminate veneers)
Restorations**



MAY 19 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Newave Medical, Incorporated
C/O Ms. Jacqueline E. Masse
Senior Consultant
70 Walnut Street
Wellesley, Massachusetts 02181

Re: K980018
Trade Name: CRISTOBAL
Regulatory Class: II
Product Code: EBF
Dated: April 2, 1998
Received: April 3, 1998

Dear Ms. Masse:

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.

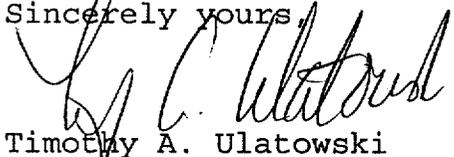
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, 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) 594-4692. 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" (21CFR 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/dsma/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): K980018

Device Name: **CRISTOBAL**

Indications For Use:

To construct cosmetic prosthetic dental restoratives for use in fixed restorations with or without metal frameworks to include:

- single crowns,
- telescope crowns,
- conus crowns,
- bridges,
- Maryland bridges,
- bridges on implants,
- inlays,
- onlays
- facettes (lamine veneers), and
- restorations.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Ringer
Division Sign-Off
Division of Dental,
and General Hospital De
510(k) Number K980018

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use