

SEP 22 1998

[CHROMA ZONE COLOR STAIN, Kuraray]



KURARAY CO., LTD.

12-39, 1-Chome, Umeda, Kita-ku, Osaka 530-8611, JAPAN
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K982259

510(K) SUMMARY

1. Submitter

- 1) Name KURARAY CO., LTD.
- 2) Address 1-12-39, Umeda, Kita-ku, Osaka 530-8611, Japan
- 3) Telephone 81(Japan)6-348-2603
- 4) Facsimile 81(Japan)6-348-2552
- 5) Contact person Yoshinori Nagase
Dental Material Department
Medical Products Division
- 6) Date June 25, 1998

2. Representing (Subsidiary of KURARAY CO., LTD)

- 1) Name KURARAY AMERICA Inc.
- 2) Address 30th Fl. Metlife Building, 200 Park Avenue, New York, NY 10166
- 3) Telephone (212)986-2230
- 4) Facsimile (212)876-3543
- 5) Contact person Koji Fijita
President

3. Name of Device

- 1) Proprietary Name CHROMA ZONE COLOR STAIN
- 2) Classification Name Tooth shade resin material (21CFR 872.3690)
- 3) Common/Usual Name Resin-based stain material

4. Predicate devices:

- 1) TARGIS SYSTEM by IVOCLAR NORTH AMERICA, INC. (K962878)
- 2) BELLEGLASS HP DENTAL LABORATORY CROWN AND BRIDGEBUILDING SYSTEM by KERR CORP. (K955331)
- 3) ARTGLASS & KEVLOC by HERAEUS KULZER, INC. (K954115)
- 4) SOLIDEX by SHOFU DENTAL CORP. (K972292)
- 5) FIBREKOR by JENERIC/PENTRON, INC. (K964578)
- 6) DENTACOLOR VITA(VS) SHADE SYSTEM by HERAEUS KULZER, INC. (K940800)

5. Description for the premarket notification

CHROMA ZONE COLOR STAIN is classified into tooth shade resin material, CFR 21 Section 872.3690, because it is a device composed of materials such as dimethacrylate monomers and inorganic fillers intended to be used for laboratory fabrication of jacket crown, facing crown, inlay and onlay restorations.

This product is similar and substantially equivalent in design, composition and function to stain materials of the similar products which are identified in the paragraph 4 of this

summary; all of which are safe, effective and beneficial.

6. Statement of the intended use.

This device is used for developing color characterization of resin-based facing crown, jacket crown, and inlay and onlay restorations. The indication is same to that of stain materials in similar products.

- | | |
|---|-----------|
| 1) TARGIS SYSTEM by IVOCLAR NORTH AMERICA, INC. | (K962878) |
| 2) BELLEGLASS HP DENTAL LABORATORY CROWN AND BRIDGEE FABLICATION SYSTEM by KERR CORP. | (K955331) |
| 3) ARTGLASS & KEVLOC by HERAEUS KULZER, INC. | (K954115) |
| 4) SOLIDEX by SHOFU DENTAL CORP. | (K972292) |
| 5) FIBREKOR by JENERIC/PENTRON, INC. | (K964578) |
| 6) DENTACOLOR VITA(VS) SHADE SYSTEM by HERAEUS KULZER, INC. | (K940800) |

7. Statement of the technological characteristics and safety

CHROMA ZONE COLOR STAIN is developed to be used for color characterization in laboratory fabrication of resin-based jacket crown, facing crown, inlay and onlay. CHROMA ZONE COLOR STAIN is substantially equivalent in design, components and function to that of products sold in the U.S. market.

7-1 Components

CHROMA ZONE COLOR STAIN consists of 11 Stain Pastes, the Clear Paste and accessories. These components are similar to that of stain materials of the products in the paragraph 4 of this summary.

7-2 Technological characteristics

In general, resin-based crown and bridge materials consists of body resin such as transparent, enamel and dentin, opaque resin, stain and accessories. CHROMA ZONE COLOR STAIN is a stain material for color characterization to be used in conjunction with resin-based crown and bridge materials. CHROMA ZONE COLOR STAIN is substantially equivalent in intended use and performance to that of products sold in the U.S. market.

There are two methods for color characterization. One method is to put a stain material to dentin resin and place enamel resin on it.(Inner stain technique) The other method is to put a stain material to pit and fissure site after shaping and polishing.(Surface stain technique) CHROMA ZONE COLOR STAIN is used by these methods and the procedure is same to that of products sold in the U.S. market.

CHROMA ZONE COLOR STAIN is substantially equivalent in design, components and function to that of products sold in the U.S. market.

7-3 Chemical ingredients

The chemical ingredients except BGP, DTA, JFB2 and JFB404 have been already used in the following products that is allowed to be sold in U.S. market.

- | | |
|---|-----------|
| 1. CLEARFIL LINER BOND 2 by Kuraray Co., Ltd. | (K943169) |
| 2. PANAVIA 21 by Kuraray Co., Ltd. | (K933030) |
| 3. CLEARFIL POSTERIOR 3 by Kuraray Co., Ltd. | (K871635) |
| 4. PHOTO CLEARFIL OPAQUER by Kuraray Co., Ltd. | (K925383) |
| 5. TEETHMATE F-1 by Kuraray Co., Ltd. | (K965091) |
| 6. CLEARFIL LINER BOND 2V by Kuraray Co., Ltd. | (K974486) |
| 7. CLEARFIL AP-X by Kuraray Co., Ltd. | (K943168) |
| 8. PANAVIA EX; A Dental Adhesive by Kuraray Co., Ltd. | (K855211) |
| 9. DURAFILL MICROFILL RESTORATIVE MATERIAL
by Kulzer, Inc. | (K811669) |
| 10. PRISMA-FIL by DENTSPLY INTL. | (K801732) |

Both JFB2 and JFB404 do not affect safety of CHROMA ZONE COLOR STAIN, because it is a food additive and a same pigment is listed as a color additive in 21 CFR.

BGP is a borosilicate glass containing SiO₂, B₂O₃, Al₂O₃, Na₂O, K₂O and Fe₂O. These metallic oxides are used as ingredients of dental porcelain.

8. Summary of biological evaluation

The biocompatibility of BGP and DTA is as follows. These results suggest that CHROMA ZONE COLOR STAIN is a safe dental device.

8-1 BGP(used as inorganic filler)

8-1-1 Acute toxicity

- | | |
|-----------------|--|
| 1) Animal | Mouse |
| 2) Dosing route | Oral |
| 3) Results | LD ₅₀ ; not less than 8,000 mg/kg |

8-2 DTA(used as matrix resin)

8-2-1 Acute toxicity

- | | |
|-----------------|--|
| 1) Animal | Rat |
| 2) Dosing route | Oral |
| 3) Results | LD ₅₀ ; not less than 3,000 mg/kg |

8-2-2 Genotoxicity test

- | | |
|------------|-----------|
| 1) Method | Ames test |
| 2) Results | Negative |



SEP 22 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Kuraray Co., Ltd.
C/O Mr. Koji Fujita
President
Kuraray America, Incorporated
30th FI Metlife Building
200 Park Avenue
New York, New York 10166-3098

Re: K982259
Trade Name: Chroma Zone Color Stain
Regulatory Class: II
Product Code: EBF
Dated: June 26, 1998
Received: June 26, 1998

Dear Mr. Fujita:

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 (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 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,


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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): _____
Device Name: CHROMA ZONE COLOR STAIN

Indications for Use

Color characterization for:

- 1) Jacket crown
- 2) Facing crown
- 3) Inlay and onlay

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use OR Over-The-Counter Use

(Optional Format 1-2-96)



(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number 1K982259