



KURARAY CO., LTD.

12-39, 1-Chome, Umeda, Kita-ku, Osaka 530-8611, JAPAN
 Phone : +81-6-348-2603
 Facsimile: +81-6-348-2552

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 | September 28, 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)-867-3543 |
| 5) Contact person | Koji Fujita
President |

3. Name of Device

- | | |
|------------------------|---------------------------------|
| 1) Proprietary Name | PANAVIA F |
| 2) Classification Name | Dental Cement (21 CFR 872.3275) |
| 3) Common/Usual Name | Dental Adhesive |

4. Predicate devices:

- | | | |
|----|--|-----------|
| 1. | PANAVIA 21 by Kuraray Co., Ltd. | (K933030) |
| 2. | VARIOLINK II by Ivoclar North America Inc. | (K971372) |
| 3. | C&B META BOND by Percell | (K960464) |

5. Description for the premarket notification

PANAVIA F is classified into dental cement, CFR 21 Section 872.3275, because it is a device composed of materials such as dimethacrylate monomers and inorganic fillers intended to be used for cementation of dental devices such as crowns or bridges.

This product is similar and substantially equivalent in design, composition and function to dental cement of the 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 cementation of dental devices such as crowns or bridges. The indication is same to that of dental cements as shown blow.

- 1) Cementation of metal crowns and bridges, inlays and onlays
 1. PANAVIA 21 by Kuraray Co., Ltd. (K933030)
 2. C&B META BOND by Perrell (K960464)
- 2) Cementation of porcelain crowns, inlays and onlays.
 1. PANAVIA 21 by Kuraray Co., Ltd. (K933030)
 2. VARIOLINK II by Ivoclar North America Inc. (K971372)
- 3) Cementation of composite resin crowns, inlays and onlays
 1. PANAVIA 21 by Kuraray Co., Ltd. (K933030)
 2. VARIOLINK II by Ivoclar North America Inc. (K971372)
- 4) Cementation of adhesion bridges and splints
 1. PANAVIA 21 by Kuraray Co., Ltd. (K933030)
 2. C&B META BOND by Perrell (K960464)
- 5) Cementation of metal cores and prefabrication posts
 1. PANAVIA 21 by Kuraray Co., Ltd. (K933030)
- 6) Bonded amalgam restorations
 1. PANAVIA 21 by Kuraray Co., Ltd. (K933030)

7. Statement of the technological characteristics and safety

PANAVIA F is modified in its components and chemical substances from those in PANAVIA 21 permitted to be marketed (K933030). These modifications do not affect the safety and effectiveness.

7-1 Technological characteristics

PANAVIA F is a resin based cement cured chemically and by visible light activation, and the improved device of PANAVIA 21. There are two major improvements; the curing method and introduction of the metal adhesion primer (ALLOY PRIMER, K974089). These improvements are not affect on the performance of PANAVIA 21.

This device consists of Paste (A and B pastes), ED Primer (Liquids A and B), ALLOY PRIMER, Oxyguard II, and accessories. These components are similar to that of dental cements of the products as shown blow.

1. PANAVIA 21 by Kuraray Co., Ltd. (K933030)
2. VARIOLINK II Ivoclar North America Inc. (K971372)
3. C&B META BOND by Perrell (K960464)

The indication of PANAVIA F is same as those of the above devices sold in U.S. market. (The detail information is described in the paragraph 6 of this summary.) The usage of PANAVIA F is also similar to those of PANAVIA 21 used in conjunction with ALLOY PRIMER except the curing method. This device can be cured chemically and by visible light activation. The curing method is similar to that for PANAVIA 21 and VARIOLINK II.

Therefore, PANAVIA F is substantially equivalent in intended use and performance to that of products sold in the U.S. market.

7-2 Chemical ingredients and safety

The chemical ingredients have been already used in the following products that is allowed to be sold in U.S. market. The safety of this material is substantially equivalent to predicate devices.

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|----|---|-----------|
| 1. | PANAVIA 21 by Kuraray Co., Ltd. | (K933030) |
| 2. | PANAVIA EX by Kuraray Co., Ltd. | (K855211) |
| 3. | CLEARFIL LINERBOND 2V by Kuraray Co., Ltd. | (K974486) |
| 4. | CLEARFIL TEETHMATE F-1 by Kuraray Co., Ltd. | (K965091) |
| 5. | ALLOY PRIMER by Kuraray | (K974089) |
| 6. | DELTON PLUS by Dentsply | unknown |
| 7. | FLUOREVER PIT AND FISSURE SEALANT by
Macrochem Corp. | (K890494) |

[Note]

DELTON PLUS is thought to be the same product as DELTON F (K951296).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 1998

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: K983361
Trade Name: PANAVIA F
Regulatory Class: II
Product Code: EMA
Dated: September 24, 1998
Received: September 24, 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 (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

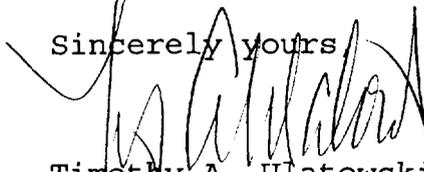
Page 2 - Mr. Fujita

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

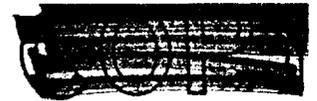


Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K983361

Page 1 of 1



510(k) Number (if known): K 98 3361

Device Name: PANAVIA F

Indications For Use:

PANAVIA F is indicated for the following applications:

- 1) Cementation of metal crowns and bridges, inlays and onlays.
- 2) Cementation of porcelain crowns, inlays and onlays.
- 3) Cementation of to composite resin crowns, inlays and onlays
- 4) Cementation of adhesion bridges and splints
- 5) Cementation of metal cores and prefabrication posts
- 6) Bonded amalgam restorations

(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 Puro

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

510(k) Number K98 3361