



KURARAY CO., LTD.

12-39, 1-Chome, Umeda, Kita-ku, Osaka 530-8611, JAPAN
Phone : +81-6-348-2603
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K982164
[ESTENIA, Kuraray]

AUG 10 1998

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 3, 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 | ESTENIA |
| 2) Classification Name | Tooth shade resin material (21CFR 872.3690) |
| 3) Common/Usual Name | Resin-based crown and bridge material |

4. Predicate devices:

- | | |
|---|-----------|
| 1) TARGIS SYSTEM by IVOCCLAR NORTH AMERICA, INC. | (K962878) |
| 2) BELLEGLASS HP DENTAL LABORATORY CROWN AND BRIDGRE 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) CONQUEST CRYSTAL by JENERIC/PENTRON, INC. | (K932154) |

5. Description for the premarket notification

ESTENIA 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 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 the following indications. Each indication is same to that of similar products.

1) Jacket crown

- | | |
|---|-----------|
| 1) TARGIS SYSTEM by IVOCCLAR NORTH AMERICA, INC. | (K962878) |
| 2) BELLEGLASS HP DENTAL LABORATORY CROWN AND BRIDGRE FABLICATION SYSTEM by KERR CORP. | (K955331) |
| 3) ARTGLASS & KEVLOC by HERAEUS KULZER, INC. | (K954115) |
| 4) FIBREKOR by JENERIC/PENTRON, INC. | (K964578) |

2) Facing crown

- | | |
|---|-----------|
| 1) TARGIS SYSTEM by IVOCCLAR NORTH AMERICA, INC. | (K962878) |
| 2) BELLEGLASS HP DENTAL LABORATORY CROWN AND BRIDGRE 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) |

3) Inlay and onlay

- | | |
|---|-----------|
| 1) TARGIS SYSTEM by IVOCCLAR NORTH AMERICA, INC. | (K962878) |
| 2) BELLEGLASS HP DENTAL LABORATORY CROWN AND BRIDGRE FABLICATION SYSTEM by KERR CORP. | (K955331) |
| 3) ARTGLASS & KEVLOC by HERAEUS KULZER, INC. | (K954115) |
| 4) FIBREKOR by JENERIC/PENTRON, INC. | (K964578) |

7. Statement of the technological characteristics and safety

ESTENIA is developed to be used for laboratory fabrication of jacket crown, facing crown, inlay and onlay. ESTENIA is substantially equivalent in design, components and function to that of products sold in the U.S. market.

7-1 Components

ESTENIA consists of Body Resin, Opaque Resin, Opaque Primer, Modeling Liquid, Add-on Primer, Air-Barrier Paste and accessories. These components are similar to that of the products in the paragraph 4 of this summary.

7-2 Applicable standard

There is an ISO standard, ISO 10477:1992, applicable to resin-based crown and bridge materials. This standard covers polymer-based crown and bridge materials for anterior restoration, and has the classification on their activation system. This standard is not applicable to ESTENIA because of following reasons.

- a) ESTENIA can not be classified according to the section 4 of this standard because of its special activation system; i.e., light-activation plus heat-activation.
- b) The intended purpose of ESTENIA includes posterior crown including stress-bearing

areas.

Following physical properties of Body Resin, Enamel, Dentin, Cervical and Transparent are evaluated with modified test methods. All specimens were prepared under light and heat polymerization. All test results fulfill the requirements of ISO 10477 excluding the test methods.

- a) Light-curing according to the final polymerization condition described in the draft instructions for use.
- b) Heat-curing according to the draft instructions for use after light-curing.

	Transparent	Enamel	Dentin	Cervical
1) Flexural strength (MPa)	135	157	175	107
Flexural modulus (MPa)	1.7×10^4	2.3×10^4	1.9×10^4	2.3×10^4
Minimum strength (MPa)	83	98	88	71
2) Water absorption ($\mu\text{g}/\text{mm}^3$)	11	7	7	8
3) Solubility ($\mu\text{g}/\text{mm}^3$)	-2	-3	-3	-2
4) Colour stability	no change	no change	no change	no change

The reason for minus values of solubility maybe came from the storing conditions specified in the test clause of ISO 10477.

7-3 Mechanical strength in comparison with predicated devices

To compare performance of ESTENIA with that of the predicated device, compressive strength and flexural strength are evaluated using the house test methods. The mechanical strengths of ESTENIA are substantially equivalent to that of products sold in the U.S. market.

	ESTENIA	CONQUEST	ARTGLASS
Compressive strength (MPa)	620	473	340
Flexural strength* ¹ (MPa)	202	160	121

*1: Preparation method of sample specimen is different from that described in 7-2.

7-4 Chemical ingredients

The chemical ingredients except AL-C, MUS, MPA, HD, DMAEM, JFB2 and POSL 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. HELIOSIT by Vivadent (USA) Inc. (K802683)
10. DENTACOLOR VITA(VS) SHADE SYSTEM by Heraeus Kulzer Inc. (K940800)

JFB2 dose not affect safety of ESTENIA, because it is a food additive and a same pigment is listed as a color additive in 21 CFR. POSL does not affect safety of ESTENIA, because a same agent is listed in NF and the component containing POSL is washed away after fabrication of restoration.

8. Summary of biological evaluation

The biocompatibility of AL-C, MUS, MPA, DMAEM and HD were evaluated its acute toxicity (LD50) and genotoxicity. Additionally, oral mucos membrane irritation test and maximization test were performed with cured Body Resin. Furthermore, acute toxicity of leachables was investigated on Body Resin, Opaque with Opaque Primer and Modeling liquid. These results suggest that ESTENIA is a safe dental device.

8-1 AL-C

8-1-1 Acute toxicity

- 1) Animal Mouse
- 2) Dosing route Oral
- 3) Results LD₅₀; not less than 3,000 mg/kg

8-1-2 Genotoxicity test

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

Bacterial species	Genotoxicity	
	with S-9 mix	without S-9 mix
<i>Salmonella typhimurium</i> TA100	Negative	Negative
<i>Salmonella typhimurium</i> TA1535	Negative	Negative
<i>Escherichia coli</i> WP2 <i>uvrA</i>	Negative	Negative
<i>Salmonella typhimurium</i> TA98	Negative	Negative
<i>Salmonella typhimurium</i> TA1537	Negative	Negative

This test was based on ISO 10993-3: 1992, biological evaluation of medical devices-part 3.

8-2 MUS

8-2-1 Acute toxicity

- 1) Animal Mouse
- 2) Dosing route Oral
- 3) Results LD₅₀; not less than 8,000 mg/kg

8-2-2 Genotoxicity test

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

Bacterial species	Genotoxicity	
	with S-9 mix	without S-9 mix
<i>Salmonella typhimurium</i> TA100	Negative	Negative
<i>Salmonella typhimurium</i> TA1535	Negative	Negative
<i>Escherichia coli</i> WP2 <i>uvrA</i>	Negative	Negative
<i>Salmonella typhimurium</i> TA98	Negative	Negative
<i>Salmonella typhimurium</i> TA1537	Negative	Negative

This test was based on ISO 10993-3: 1992, biological evaluation of medical devices-part 3.

8-3 MPA

8-3-1 Acute toxicity

- | | |
|-----------------|--|
| 1) Animal | Mouse |
| 2) Dosing route | Oral |
| 3) Results | LD ₅₀ ; not less than 4,000 mg/kg |

8-3-2 Genotoxicity test

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

Bacterial species	Genotoxicity	
	with S-9 mix	without S-9 mix
<i>Salmonella typhimurium</i> TA100	Negative	Negative
<i>Salmonella typhimurium</i> TA1535	Negative	Negative
<i>Escherichia coli</i> WP2 <i>uvrA</i>	Negative	Negative
<i>Salmonella typhimurium</i> TA98	Negative	Negative
<i>Salmonella typhimurium</i> TA1537	Negative	Negative

This test was based on ISO 10993-3: 1992, biological evaluation of medical devices-part 3.

8-4 HD

8-4-1 Acute toxicity

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

8-4-2 Genotoxicity test

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

Bacterial species	Genotoxicity	
	with S-9 mix	without S-9 mix
<i>Salmonella typhimurium</i> TA100	Negative	Negative
<i>Salmonella typhimurium</i> TA1535	Negative	Negative
<i>Escherichia coli</i> WP2 <i>uvrA</i>	Negative	Negative
<i>Salmonella typhimurium</i> TA98	Negative	Negative
<i>Salmonella typhimurium</i> TA1537	Negative	Negative

This test was based on ISO 10993-3: 1992, biological evaluation of medical devices-part 3.

8-5 DMAEM

8-5-1 Acute toxicity

- | | |
|-----------------|--|
| 1) Animal | Mouse |
| 2) Dosing route | Oral |
| 3) Results | LD ₅₀ ; not less than 2,055 mg/kg |

8-5-2 Genotoxicity test

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

Bacterial species	Genotoxicity	
	with S-9 mix	without S-9 mix
<i>Salmonella typhimurium</i> TA100	Negative	Negative
<i>Salmonella typhimurium</i> TA1535	Negative	Negative
<i>Escherichia coli</i> WP2 <i>uvrA</i>	Negative	Negative
<i>Salmonella typhimurium</i> TA98	Negative	Negative
<i>Salmonella typhimurium</i> TA1537	Negative	Negative

This test was based on ISO 10993-3: 1992, biological evaluation of medical devices-part 3.

8-6 Oral mucos membrane irritation test of cured resin

- 1) Animal Hamster
- 2) Sample ESTENIA cured Body resin
- 3) Results Negative

This test was based on ANSI/ADA document No.41 (1979) for biological evaluation of dental materials.

8-7 Sensitization test (Maximization test) of cured resin

- 1) Method Maximization sensitization test
- 2) Results Negative

This test was based on ISO 10993-10: 1992, biological evaluation of medical devices-part 3.

8-8 Acute toxicity of leachables

Cured specimens of Body Resin, Opaque with Opaque Primer, and Modeling Liquid were prepared to evaluate the acute toxicity of leachables from ESTENIA.

- 1) Sample
 - a) Body Resin(Transparent)
 - b) Body Resin(Enamel)
 - c) Body Resin(Dentin)
 - d) Opaque with Opaque primer
 - e) Modeling liquid
- 2) Extracted media Distilled water
- 3) Animal Mouse ICR
- 4) Route of administraction
 Three lots of each sample is evaluated. Cured specimens were immersed into distilled water in the ratio of 10ml/1g-specimen and stored at 80°C for one hour. The extracted fluid was administrated to 10 mouse intraorally. The administrate amount was 20ml/kg-mouse. Three lots and one reference were evaluated for each sample. After seven days, weight change of each mouse was obtained.
- 5) Result There was no group indicating weight change and no mouse died.



AUG 10 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: K982164
Trade Name: ESTENIA
Regulatory Class: II
Product Code: EBF
Dated: June 15, 1998
Received: June 19, 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

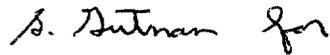
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the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

K982164
[ESTENIA, Kuraray]

510(k) Number (if known): K982164
Device Name: ESTENIA

Indications for Use

- 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)

Suzanne P. ...

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

510(k) Number K982164

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