

K072643

510(k) Summary

- **Owner/Submitter:** OLYMPUS CORPORATION
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Title: Manager, Quality Assurance and
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Date of Preparation: September 10, 2007
- **Device Trade Name:** "Crystaleye Spectrophotometer/
Crystaleye Basic Set CE100-DC/US"
("Crystaleye Device")
- **Common Name:** Scanner, Color
- **Classification Name:** Optical Impression Systems for CAD/CAM
(21 C.F.R. §872.3661)

■ **Legally Marketed Device for which equivalence is claimed:**

The predicate devices for the Crystaleye Device are the multiple shade guides and shade teeth sets for manual color evaluation and matching, including the following: VITAPAN CLASSICAL Shade Guide, VITA SYSTEM 3D-MASTER Tooth Guide, IVOCLAR VIVADENT CHROMASCOP, NORITAKE Shade Guide, and VINTAGE HALO NCC. The Crystaleye Device utilizes the tooth shades from these shade guides in its shade-matching database.

■ **Description of Device:**

The Crystaleye Device is an automated color shade-matching device, based upon a database of reference tooth shades. The Crystaleye Device is comprised of the following components: Spectrophotometer, AC Adapter, Cradle, Contact Cap (5 pcs.), AC Cable, USB Cable, Master CDs, and Instructions. A personal computer is also required to run the Master CDs. The reference color tooth shades of multiple dental restoration manufacturers are loaded into the computer. The spectrophotometer captures an image of the target tooth, and the software matches a patient's color tooth shade with the closest available shade in the computerized reference database.

■ **Intended Use of Device:**

The Crystaleye Spectrophotometer/Crystaleye Basic Set CE100-DC/US is intended for use in automated color shade-matching to assist in dental restoration. The targeted teeth for color analysis are the left and right central incisors, lateral incisors and canines.

■ **Summary of Technological Characteristics Compared to Predicate Devices:**

The Crystaleye Device utilizes the reference tooth shades of multiple dental restoration manufacturers, which are the predicate devices. Currently, use of the predicate devices requires the manual comparison of multiple tooth shades to a patient's individualized tooth shade to achieve the closest match. The Crystaleye Device automates that matching function through use of a Spectrophotometer and a computerized database of the tooth shades available from each manufacturer. The dental or medical personnel can then visually evaluate the "match" identified by the Crystaleye Device.

■ **Discussion of Non-Clinical Tests:**

Bench testing was conducted on the Crystaleye Device. Five tooth color shades (with three measurement points each) were randomly selected from each of the five sets of reference shades from multiple dental restoration device manufacturers. The Crystaleye Device was then tested three times for each set of manufacturer shades to determine if the device correctly identified the same manufacturer shade from its database of tooth shades available from each manufacturer. Thus, the Crystaleye Device was subjected to 225 test evaluations, *i.e.* 5 shades per set x 3 measurement points per shade x 5 sets x 3 tests. The Crystaleye Device correctly identified the color shade for each of the 225 test evaluations.

■ **Assessment of Clinical Performance Data:**

The Premarket Notification does not rely upon any clinical performance data. A summary of a presentation on clinical usage and experience is included as Ref. 1 (Attachment 9). S. Ishikawa-Nagai, et al., "Summary of Presentations Made at American Association of Dental Research 2006 and International Association of Dental Research 2006 and Clinical Cases from Ongoing Study" (2007).

■ **Conclusions Drawn from Non-Clinical Tests:**

The Crystaleye Device provides a color match identification which medical and dental personnel may visually evaluate quickly without manually attempting to match multiple color shades. The Crystaleye Device substantially improves the ease and accuracy of color shade-matching of teeth for dental restoration.



Food and Drug Administration
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NOV 16 2007

Olympus Corporation
C/O Fumiaki Kanai, Ph.D.
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Tokyo, 113-0034
JAPAN

Re: K072643

Trade/Device Name: Crystaleye Spectrophotometer/Crystaleye Basic
Set CE100-DC/US

Regulation Number: 21 CFR 872.3661

Regulation Name: Optical Impression Systems for CAD/CAM

Regulatory Class: II

Product Code: KZN

Dated: September 18, 2007

Received: September 18, 2007

Dear Dr. Kanai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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.

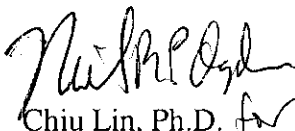
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D. *for*

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): 12072643

Device Name: "Crystaleye Spectrophotometer/Crystaleye Basic Set CE100-DC/US"

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Prescription Use AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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