May 3, 2018

Dear Ms. Ambrecht:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known)
K171007

Device Name

Fluorescence Mode

Indications for Use (Describe)
The Fluorescence Mode is intended to be used by dentist as an aid in the detection of dental caries

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY
(per 21 CFR §807.92)
Fluorescence Mode

GENERAL INFORMATION
Applicant: Carl Zeiss Suzhou Co., Ltd.
Modern Industrial Square 3b
No. 333 Xing Pu Road Sip
Suzhou, Jiangsu 215126 China
+ 86-512-8227-1388 (phone)
+ 86-512-6287-1366 (fax)
Establishment Registration Number: 3008564898

Contact Person: Mandy Ambrecht
Staff Regulatory Affairs Specialist
Carl Zeiss Meditec, Inc.
5160 Hacienda Drive
Dublin, CA 94568
(925) 557-4561 Phone
E-mail: mandy.ambrecht@zeiss.com

Date Prepared: May 3, 2018

Common Name: Dental Fluorescence Examination Device
Classification Name: Laser Fluorescence Caries Detection Device
Product Code and Class: NBL – Class II
Classification Number: 21 CFR 872.1745
Trade/Proprietary Name: Fluorescence Mode
**PREDICATE DEVICE**

Company: Durr Dental AG

Device: VistaCam iX “Proof” (K150672)

It is the opinion of Carl Zeiss Suzhou Company, Limited that the dental Fluorescence Mode of the EXTARO 300 surgical microscope is substantially equivalent to the predicate VistaCam iX “Proof” (K150672) for the intended use as an aid in the detection of dental caries. The Fluorescence Mode built-in to the surgical microscope aids in the detection of caries.

**INDICATIONS FOR USE (21 CFR §807.92(a)(5))**

The Fluorescence Mode is intended to be used by dentist as an aid in the detection of dental caries.

**DEVICE DESCRIPTION SUMMARY (21 CFR §807.92(a)(4))**

CZSZ currently manufactures an optional accessory, Fluorescence Mode, to the EXTARO 300 intended to be used by dentist as an aid in the detection of dental caries.

Device Overview

The Fluorescence Mode is an accessory to the EXTARO 300 surgical microscope to utilize a kind of LED light that illuminates the tooth surfaces in the visible domain in the blue light region with a narrow band (around wavelength 405nm).

The Fluorescence Mode is not a standalone device. It is a built-in feature (new components) to existing surgical microscope. These components include (1) an additional violet source in existing LED lamp, (2) a bandpass filter in existing OPMI (Operation Microscope) Head and (3) multi-function knob on existing OPMI Head.

The primary operating functions of EXTARO 300 are:

- to provide a view of the surgical field with variable magnification,
- to illuminate the surgical field,
- to provide means to move the microscope to the surgical field, and,
- to hold it in this position while viewing the surgical procedure.

The primary operating functions are realized by the viewing optics in the microscope, the illumination system, and the microscope stand/suspension system.
Description of Software

Software of the EXTARO 300 surgical microscope provides the firmware control following functionalities:

- Light source control
- Filter control
- Video control
- Communication with iPad
- Wi-Fi module has access control

CZSC has implemented a software development process according to IEC 62304 for software with a Moderate Level of Concern.

Risk Management

Carl Zeiss Suzhou Co., Ltd. has implemented and maintains a risk management assessment process according to ISO 14971. This process which is defined in an internal Standard Operation Procedure was conducted on EXTARO 300.

The device labeling contains instructions for use and any necessary cautions and warnings for use of the device.

Risk management is ensured via a risk analysis, which is used to identify potential hazards and mitigations. These potential hazards are controlled by software means, user instructions, verification of requirements and validation of the clinical workflow to ensure that the product meets its intended uses. To minimize electrical, mechanical and radiation hazards, ZEISS adheres to recognized and established industry practice and relevant international standards.

Technological Characteristics and Substantial Equivalence (21 CFR §807.92(a)(6)):

It is the opinion of CZSZ that the proposed device, the dental Fluorescence Mode of the EXTARO 300 surgical microscope, is substantially equivalent to the predicate VistaCam iX “Proof” (K150672).

The indications for use for the Fluorescence Mode of the EXTARO 300 surgical microscope is similar to the indications for the predicate device VistaCam iX “Proof” (K150672).

Technological and functionalities comparisons demonstrate that the Fluorescence Mode of the EXTARO 300 surgical microscope is functionally equivalent to the primary predicate VistaCam iX “Proof” (K150672) and does not raise new questions regarding safety and effectiveness.

Non-Clinical Performance Testing (21 CFR §807.92(b)):

There were several devices identified to already be on the market which were considered similar or equivalent to Fluorescence mode based on EXTARO 300 surgical microscope. Due to non-contact operation of this fluorescence module and surgical microscope with the patient, it has a very low surgical risk profile. The verification and validation test of the Fluorescence Mode based on EXTARO 300 have generated data to provide evidence of substantial equivalence.
The Fluorescence Mode of the EXTARO 300 surgical microscope is designed and tested to applicable standards for electrical and optical safety with established specifications. Performance testing conducted on the system was consistent to the intended use claim. The verification testing demonstrates that the device performance complies with specifications and requirements. Results of verification and validation demonstrate substantially equivalent safety and effectiveness as the predicate device; tests can be categorized into the following groups:

- Device System Verification
- Verification According to Harmonized/Recognized Standards
  - Electromagnetic Compatibility and Electrical Safety
  - Environmental Simulation
  - Usability
- Software Verification and Validation
- Product Validation

**Testing to Consensus Standards (21 CFR §807.92(b)(1))**

The Fluorescence Mode of EXTARO 300 surgical microscope has been tested (as needed) to meet the requirements for conformity (where applicable) to multiple industry standards. The R&D evaluation of the relevant testing to consensus standards is documented and listed as below.

<table>
<thead>
<tr>
<th>No.</th>
<th>Performance testing</th>
<th>Standard followed</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Light Safety Testing</td>
<td>IEC 62471:2006/EN 62471:2008 Photobiological safety of lamps and lamp systems</td>
<td>Testing has demonstrated the fluorescence mode conforms to the requirements of current FDA recognized standard, IEC 62471:2006 Photobiological safety of lamps and lamp systems.</td>
</tr>
<tr>
<td>2</td>
<td>Environmental Testing</td>
<td>N/A</td>
<td>The Environmental testing demonstrated that the performance of products were not changed after various environmental testing parameters, including temperature, simulated transportation, moisture, and pressure.</td>
</tr>
<tr>
<td>3</td>
<td>Usability Testing</td>
<td>IEC 62366-1 : 2015 Medical devices -- Part 1: Application of usability engineering to medical devices</td>
<td>Usability testing demonstrated that the device could be used by the intended users without serious use errors or problems, for the intended uses and under the expected use conditions. This testing involved total 15 clinicians and</td>
</tr>
<tr>
<td>No.</td>
<td>Performance testing</td>
<td>Standard followed</td>
<td>Conclusion</td>
</tr>
<tr>
<td>-----</td>
<td>---------------------</td>
<td>-------------------</td>
<td>------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>12 sites, who used Fluorescence Mode to aid in the detection of caries in more than 40 cases in clinical practices.</td>
</tr>
<tr>
<td>4</td>
<td>System Verification Testing</td>
<td>ISO 10936-1:2000 Optics and photonics -- Operation microscopes -- Part 1: Requirements and test methods</td>
<td>System verification testing demonstrated that all System Requirement Specifications were met, including those for product stability, ergonomics, dimensions, image quality, image filters, and light sources.</td>
</tr>
<tr>
<td>6</td>
<td>Software Verification and Validation Testing</td>
<td>N/A</td>
<td>Software V&amp;V was performed in accordance with FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices for a device of Moderate Level of Concern.</td>
</tr>
<tr>
<td>7</td>
<td>Background light interference verification.</td>
<td>N/A</td>
<td>Testing demonstrated that expected levels of background light do not impact the performance of the device. A light intensity of 40lx for CCT 4000K-6500K light was selected as an acceptable level of background light in the exam room. Testing across the spectrum of 4000K-6500K background light sources has demonstrated that the carious teeth can be differentiated at 40lx and below.</td>
</tr>
</tbody>
</table>
**Substantial Equivalence to Predicates** (21 CFR §807.92(b)(1))

Verification testing to the system requirements (SRS) for the Fluorescence Mode and the validation of the intended use is intended to support the claim of substantial equivalence to the following Substantial Equivalence table:

Table 1: Substantial Equivalence Table (abbreviated)

<table>
<thead>
<tr>
<th>Device</th>
<th>The Fluorescence Mode (Proposed Device)</th>
<th>VistaCam IX “Proof” (K150672)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended Use</td>
<td>The Fluorescence Mode is intended to be used by dentist as an aid in the detection of dental caries</td>
<td>Caries detection aid</td>
</tr>
<tr>
<td>Indication for Use</td>
<td>The Fluorescence Mode is intended to be used by dentist as an aid in the detection of dental caries.</td>
<td>The VistaCam IX “Proof” is intended to be used as an aid in the detection and diagnosis of dental caries.</td>
</tr>
<tr>
<td>Device Classification Name</td>
<td>Laser Fluorescence Caries Detection</td>
<td>Laser Fluorescence Caries Detection</td>
</tr>
<tr>
<td>Generic Common Name</td>
<td>Dental Fluorescence Examination Device</td>
<td>Intraoral Camera with Fluorescence Caries Detection Aid</td>
</tr>
<tr>
<td>Classification Product Code</td>
<td>NBL</td>
<td>NBL</td>
</tr>
<tr>
<td>Class</td>
<td>II</td>
<td>II</td>
</tr>
<tr>
<td>Technology</td>
<td>Fluorescence technology to aid in the detection of carious lesions</td>
<td>Fluorescence technology to aid in the detection of carious lesions</td>
</tr>
<tr>
<td>Mode of Operation</td>
<td>Excites bacteria to fluoresce</td>
<td>Excites bacteria to fluoresce</td>
</tr>
<tr>
<td>Detection Wavelength</td>
<td>405 nm</td>
<td>405 nm (Proof interchangeable head)</td>
</tr>
</tbody>
</table>

**Differences:**

<table>
<thead>
<tr>
<th>Device Operating Feature</th>
<th>Dental microscope with built-in feature provides visualization and an uninterrupted workflow</th>
<th>Headpiece with control buttons</th>
</tr>
</thead>
</table>
| Software | **Software of Surgical Microscope:**  
- Light Source Control  
- Filter Control  
- Video Control  
- Wi-Fi Module: Firmware processes network communication | Using DBSWIN Imaging Software |

The above table shows that these two devices are similar in the technological characteristics, the intended use, and the performances in detecting dental caries. Details of the Substantial Equivalence Discussion and comparison chart are in Section 12.

The differences between the subject device and the predicate device are supported by performance data and do not raise any new questions about safety and effectiveness. The device can therefore be considered substantially equivalent to the predicate device.

**510(k) Summary (21 CFR §807.92(c))**

As described in this 510(k) Summary, all testing deemed necessary was conducted on the Fluorescence Mode of the EXTARO 300 surgical microscope to ensure that the device is substantially equivalent to the predicate in terms of safety and effectiveness for its intended use when used in accordance with its Instructions for Use.