April 29, 2022

D4D Technologies, LLC
Eddie Anderson
Regulatory Affairs Manager
2920 Telecom Parkway, Suite 100
Richardson, Texas 75082

Re: K213482
Trade/Device Name: TIA Tip, Cariosity, Transillumination Accessory Tip
Regulation Number: 21 CFR 872.1745
Regulation Name: Laser Fluorescence Caries Detection Device
Regulatory Class: Class II
Product Code: NTK
Dated: March 30, 2022
Received: March 31, 2022

Dear Eddie Anderson:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See *PRA Statement below.*

51O(k) Number *(if known)*

K213482

Device Name

TIA Tip, Cariosity, Transillumination Accessory Tip, P/N 156930xx

Indications for Use *(Describe)*

The TIA Tip is a diagnostic aid for viewing the interproximal areas of dental anatomy to detect and monitor the progression of proximal carious lesions above the gingiva.

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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5.1 Sponsor / 510(k) Owner

D4D Technologies, LLC (dba E4D Technologies)
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5.2 Date Summary Prepared:

March 16, 2022

5.3 Device Name

Trade Name(s):	Cariosity; TIA Tip, Transillumination Accessory Tip
Common Name:	Caries Detector, Laser Light, Transmission
Classification Name:	Laser fluorescence caries detection device
Regulation Number:	872.1745
Product Code:	NTK
Device Class:	Class 2
Medical Specialty:	Dental

5.4 Predicate Device(s)

CamX Triton HD Proxi Head (K172007); Duerr Dental AG

5.5 Device Description

The TIA Tip is an optional interchangeable component tip assembly that works with the Dental CAD/CAM System Scanner. With the TIA Tip installed the system allows for the simultaneous side by side visualization of live transilluminated and color imaging of the patient's dental anatomy, as well as providing the user with the ability to capture and save transilluminated static images to a patient digital file. The system consists of:

- Dental Scanner
- TIA Tip
- Computer with Software

With one of the other provided interchangeable scanning tips installed, the system is also used to process dental restorations that are regulated under 21 CFR 872.3661, Optical Impression Systems for CAD/CAM of Dental Restorations.

The Scanner is a hand-held electronic device that consists of three parts: the scanner body, the TIA Tip and a custom USB data cable that connects the scanner to the computer. The scanner contains the electrical and opto-mechanical components.

The USB cable uses industry standard USB 3.0 type-A and type-C connectors, and the cable assembly is detachable making it easily replaceable.

The TIA tip must be connected to the scanner to work. It incorporates two "probes" containing Light Emitting Diodes (LEDs) that emit 727nm near infrared light.

In operation the probes conform to dental anatomy to direct light into the desired area of inspection. The light penetrates the tooth surface due to the translucent nature of dental anatomy. This allows a user to visualize the inner structure of the tooth and specifically to detect irregularities like caries that show up as dark areas or spots on the transilluminated image. The scattering light of the illuminated anatomy is reflected by the tip mirror and directed toward the camera in the scanner which allows for a digital image to be captured.

The tooth is illuminated with light from both the scanner's laser projection system (RGB) and the TIA Tip LED's. Timing of the light is controlled through the electronics and software and is divided into separate frames. Collecting and presenting these images at many frames per second allows simultaneous "live" views of transilluminated image and full color view to the system operator. This allows the user to better visualize caries that cannot be detected with standard color imaging. For example, a proximal dental cavity becomes visible as a dark region in the transilluminated image.

The software will also allow for the capture of static images throughout the inspection process if the user wishes to document an area of interest and show the patient to discuss treatment options.

The software operates on a laptop or desktop pc. A network connection is required for interoperability.

When the TIA Tip is installed, it is automatically detected by the scanner and the operator is presented with both a transilluminated view and a live view simultaneously. The operator is provided with controls on the scanner to start/stop and toggle TIA illumination from Both/Right/Left LEDs to enhance TIA viewing. Additionally, on screen controls allow for TIA illumination intensity control for further TIA view optimization. Image capture of simultaneous TIA and live view images is provided which can be used for later reference. No digitization occurs during TIA viewing.

5.5.1. Scientific Concept

The underlying scientific concept is the use of transillumination, shining light through a body area or organ to check for abnormalities. The 727nm near IR LEDs in the TIA Tip illuminate the internal layers (enamel, dentin, pulp) of a tooth and the imaging sensor in the scanner captures the images in real time. The software displays the black and white 2D transillumination images on a computer screen as a live view and can also store the images for later use. A dentist can then use the images as an aid in the detection and monitoring of caries, or other abnormalities inside the tooth.

5.6 Indications for Use

The TIA Tip is a diagnostic aid for viewing the interproximal areas of dental anatomy to detect and monitor the progression of proximal carious lesions above the gingiva.

5.7 Summary of technological characteristics / Substantial Equivalence Discussion

The following Table compares the Transillumination Accessory (TIA) Tip, P/N 156930xx to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence.

Table 5A – Comparison of Characteristics

Description	TIA Tip, P/N 156930xx K213482 (Subject Device)	CamX Triton HD Proxi Head K172007 (Predicate Device)	Device Comparison
Product Code	NTK	NTK	Same
Regulation Number	872.1745	872.1745	Same
Indications for Use	The TIA Tip is a diagnostic aid for viewing the interproximal areas of dental anatomy to detect and monitor the progression of proximal carious lesions above the gingiva.	The CamX Triton HD Proxi Head is a diagnostic aid for the detection of interproximal caries lesions above the gingiva and for monitoring the progress of such lesions.	Equivalent – Proximal and Interproximal are used interchangeably. The subject device and the predicate device both use transillumination to view the same area of the dental anatomy and for the same purposes. The difference is that when viewing from the occlusal position, the subject device projects transilluminated light from the buccal/lingual position of the tooth whereas the predicate device projects the transilluminated light from the occlusal position of the teeth.
Design	Handheld device	Handheld device	Same
Functional Principle	Transillumination: Based on the principle that tooth enamel is translucent to NIR light. If the light transmission is interrupted due to caries lesions a dark area appears, in normal mode. (Inverse CamX Triton HD Proxi Head)	Transillumination: It makes use of the tooth structure which has the ability of light transmission. If the light transmission is interrupted due to caries lesions a bright area appears.	Equivalent: Both use the principle of transillumination. The difference is that the predicate device indicates the potential carious lesions as bright spots and the TIA Tip provides alternate views in normal, inverted and color.
Device Components	Handheld device with USB, cable and software installed on a computer.	Handheld device with USB, cable and software installed on a computer.	Same
Light Source	Two LEDs are used to generate the exact wavelength being detectable by the CMOS sensor.	Two LEDs are used to generate the exact wavelength being detectable by the CMOS sensor.	Same
Installation	The computer-based installation enables the customer to update the software	The computer-based installation enables the customer to update the software	Same
Power Source	USB-5V	USB-5V	Same
Compatibility	USB 3.0 connection	USB connection	Same
Compliance to Standards	IEC 60601-1	IEC 60601-1	Same

510(k) Summary

Description	TIA Tip, P/N 156930xx K213482 (Subject Device)	CamX Triton HD Proxi Head K172007 (Predicate Device)	Device Comparison
Cross Contamination Control	Autoclave (tip of the device) The scanner body (operator contact) is covered with an FDA cleared disposable sheath or barrier material.	Camera cover (single patient disposable sheath, K132953) is placed over the distal end, and an autoclave-able spacer	The entire TIA Tip is autoclavable whereas the predicate device uses a combination of a single patient disposable sheath together with an autoclavable spacer.
Available Configurations	One Configuration: Handpiece and proprietary software. The handpiece can be connected via USB to a computer.	One Configuration: Handpiece and proprietary software. The handpiece can be connected via USB to a computer (customer provided).	Same
Software	The software is a computer-based software, which is controlling: – Show / display the pictures – Store / save the pictures – Live Stream (side by side for transilluminated and live color image) – Controlling of camera functions	The software is a computer-based software, which is controlling: – Show / display the pictures – Store / save the pictures – Live Stream – Controlling of camera functions	Equivalent – the TIA Tip has the added feature of being able to show the transilluminated live image and the color live view images side by side, whereas the predicate device only displays the live transilluminated image.
Intended Users	Dentist	Dentist	Same
Wavelength	727 nm	850 nm	the predicate device uses LEDs with a slightly higher wavelength. The higher wavelength will naturally penetrate better into the tooth. However, this is easily compensated for by adjusting the driving current for LEDs on the subject device to achieve optimal image quality.
Output Power	2 LED Sources (transillumination) – Max 3.74mW/cm^2 (1.8-1.9 mW/cm^2 for each LED) measured at the 3.845 mm measuring distance Laser (live color view) – Max 1.12mW/cm^2 at 100mm measuring distance through a 7mm aperture.	2 LED sources - Max 2.00 mW/cm^2 at 7mm measuring distance	Considering the difference in measuring distance of 3.845 vs. 7mm, the LED output power for TIA Tip and CamX Triton are almost the same as measured in side-by-side testing using the same measurement equipment and in the same test environment. The Laser power was measured by TUV in report 7169004049-100. (See page 17-489)

Description	TIA Tip, P/N 156930xx K213482 (Subject Device)	CamX Triton HD Proxi Head K172007 (Predicate Device)	Device Comparison
Illumination Type	Pulsed Illumination – method of illumination that consists of periodical light source activation. I.e. alternating ON(pulse)/OFF states.	Continuous Illumination – method of illumination in which the source is activated continuously.	The TIA Tip uses sequential pulses of RBG laser light and NIR LED light to produce side by side transillumination and color live stream images.

5.8 Summary of Nonclinical Performance Testing

The TIA Tip was evaluated to demonstrate substantial equivalence based on similar performance to the predicate device, the CamX Triton HD Proxi. Key performance attributes tested and compared include:

a. LED illumination and output power
b. Image Quality

Validation and verification test results showed that the subject device and the predicate device are substantially equivalent, and that illumination and image quality of potential caries detection products are similar for both Duerr Dental AG's CamX Triton HD Proxi and E4D's TIA Tip. The TIA Tip complies with the following:

- IEC 60601-1 Edition 3.1 – Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 – Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
- Sterilization validation was conducted in accordance with ISO 17665-1 – Sterilization of Health Care Products – Moist Heat-Part 1
- Biocompatibility Testing in accordance with the required parts of the ISO 10993 series; derived from the ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing

  There are no known biocompatibility issues associated with any patient contact materials used to manufacture the TIA Tip. The assembled tip was tested and complies with ISO 10993-10 for Irritation and Delayed Hypersensitivity, and ISO 10993-5 for Cytotoxicity.

5.9 Summary of Clinical Testing

Clinical testing is not required and has not been performed.

5.10 Conclusion

A comparison of the indications for use, construction materials, and principle of operations, features and technical data show that the TIA Tip is safe and effective for its intended use. Evaluation of the minor technological differences between the subject device and the predicate do not raise any new issues of safety or effectiveness.

Based on similarities in indications for use and technological characteristics, together with results of non-clinical performance testing, it is concluded that the TIA Tip is substantially equivalent to the CamX Triton HD Proxi Head system.