June 13, 2024

Relu BV
℅ Breanne Butler
Regulatory Specialist
Prime Path Medtech
1321 Upland Dr., Suite 6792
HOUSTON, TX 77043

Re: K233925
Trade/Device Name: Relu Creator
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: May 15, 2024
Received: May 15, 2024

Dear Breanne Butler:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Smita Kakar 2024.06.13 15:30:48 -04'00'

for

Lu Jiang
Assistant Director
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K233925

Device Name

Relu Creator

Indications for Use *(Describe)*

Relu Creator is a software program for the management, transfer, and analysis of dental and craniomaxillofacial image information, and can be used to provide design input for dental solutions. It displays and enhances digital images from various sources to support the diagnostic process and treatment planning. It stores and provides these images within the system or across computer systems at different locations.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) #: K233925

510(k) Summary

Prepared on: 2024-06-13

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Relu BV
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Correspondent Contact Telephone	860-810-5594
Correspondent Contact	Dr. Breanne Butler
Correspondent Contact Email	bbutler@primepathmedtech.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Relu Creator
Common Name	Medical image management and processing system
Classification Name	Medical image management and processing system
Regulation Number	892.2050
Product Code	QIH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K213562	DTX Studio Clinic 3.0	LLZ

Device Description Summary

21 CFR 807.92(a)(4)

The Relu Creator is a software that is part of the digital workflow of dental specialists in preoperative planning. The main purpose is the 3D modeling of the patient anatomy, which is technically called image segmentation and multimodel registration. Based on the model, simulations for preoperative and pretreatment planning can be carried out for dental applications. The 3D modeling (segmentation + registration) is performed on medical images like CBCT, IOS and FS. The preoperative/pretreatment software can be applied in various dental disciplines such as orthodontics, implantology, and maxillofacial surgery.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Relu Creator is a software program for the management, transfer, and analysis of dental and craniomaxillofacial image information, and can be used to provide design input for dental solutions. It displays and enhances digital images from various sources to support the

diagnostic process and treatment planning. It stores and provides these images within the system or across computer systems at different locations.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Based on the comparison, the indications of use of the Subject Device is similar to that of the Predicate Device. There are two differences between the indications for use of the Subject Device and Predicate Device.

One difference is in the scope of activities of Relu Creator when compared to DTX Studio. DTX Studio includes the acquisition, management, transfer, and analysis of dental and craniomaxillofacial image information. Relu creator includes only management, transfer, and analysis of dental and craniomaxillofacial image information. Relu Creator does not include the acquisition of image information.

Additionally, the indication for Relu Creator applies generally to dental solutions, rather than only to dental restorative solutions. This is because Relu Creator can be used to process image information in the dental and craniomaxillofacial area for any treatment in that region.

Based on the similarity of indication for use, the Subject Device can be considered substantially equivalent to the Predicate Device.

Technological Comparison

21 CFR 807.92(a)(6)

Based on the comparisons, the design, construction, and performance characteristics of the Subject Device are similar to that of the Predicate Devices.
The differences identified are not substantial differences in operation of the device.
Input Data: The subject device does not acquire image data, whereas the predicate device includes features for image acquisition. Otherwise, the types of imaging file data imported to the subject device are similar to the inputs of the predicate device. Both include image file types that are commonly used in the dental industry (CBCT, IOS, and FS).
Output Data: The subject device provides outputs in several formats (STL, DICOM, PLY, OBJ) that are commonly for dental and craniomaxillofacial treatment planning applications. The predicate device offers outputs in additional formats. Additionally, the predicate device provide treatment planning outputs. The subject device is intended for processing of dental and craniomaxillofacial imaging data as an input to the treatment planning process.
Image Processing: The subject device has the same general image processing features as the predicate device. However, the subject device does not include volume or surface area measurements.
Automatic Segmentation Algorithm: Relu Creator includes an automatic segmentation algorithm, which is powered by Relu Engine. The predicate device also includes a similar automatic volume segmentation algorithm.
OS/Hardware/IT Requirements: The Minimum OS, Hardware, and IT Requirements of the Subject Device are similar to that of the Predicate Device. Relu Creator is available in both web-application and local application formats. The differences between the predicate and subject device account for differences in the development framework used, but do not impact the intended use or application of the devices.
There are no other substantial differences between the technical requirements between the Subject and Predicate Devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The Subject Device has passed testing for appropriate verification and validation and performed per its intended use. Therefore, it can be substantially equivalent to its Predicate Devices.

Based on the performance testing and software validation testing, the Subject Device, Relu Creator, has been shown to be appropriate for its indications for use and is as safe and as effective than the legally marketed Predicate Device, DTX Studio 3.0 (K213562). There are no substantial differences between the indications for use, technological features, or performance testing of the Subject and Predicate Device.