Olea Medical
℅ John J. Smith
Partner
Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
WASHINGTON DC 20004

June 9, 2023

Re: K223091
Trade/Device Name: CT Perfusion V1.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: May 16, 2023
Received: May 16, 2023

Dear John Smith:

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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of 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

510(k) Number *(if known)*

K223091

Device Name

CT Perfusion V1.0

CT Perfusion V1.0 is an automatic calculation tool indicated for use in radiology. The device is an image processing software allowing computation of parametric maps from CT Perfusion data and extraction of volumes of interest based on numerical thresholds applied to the aforementioned maps. Computation of mismatch between extracted volumes is automatically provided.

The device is intended to be used by trained professionals with medical imaging education including but not limited to, physicians and medical technicians in the imaging assessment workflow by extraction and communication of metrics from CT Perfusion dataset.

The results of CT Perfusion V1.0 are intended to be used in conjunction with other patient information and, based on professional judgment, to assist the clinician in the medical imaging assessment. Trained professionals are responsible for viewing the full set of native images per the standard of care.

The device does not alter the original image. CT Perfusion V1.0 is not intended to be used as a standalone diagnostic device and shall not be used to take decisions with diagnosis or therapeutic purposes. Patient management decisions should not solely be based on CT Perfusion V1.0 results.

CT Perfusion V1.0 can be integrated and deployed through technical platforms, responsible for transferring, storing, converting formats, notifying of detected image variations and display DICOM of imaging data.

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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I. 510(K) SUMMARY

The Company's 510(k) Summary is provided on the following pages.

510(k) SUMMARY

Olea Medical's CT Perfusion V1.0

Submitter K223091

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Date Prepared: September 30, 2022

Name of Device: CT Perfusion V1.0

Common or Usual Name: Picture archiving and communication system (PACS)

Regulation Name: Medical Image Management and Processing System

Regulatory Class: 21 CFR 892.2050

Product Code: LLZ

Predicate Device: Olea Sphere V3.0 (K152602)

- Manufacturer: Olea Medical
- Regulation Number: 21 CFR 892.2050
- Product Code: LLZ

Intended Use / Indications for Use

CT Perfusion V1.0 is an automatic calculation tool indicated for use in radiology. The device is an image processing software allowing computation of parametric maps from CT Perfusion data and extraction of volumes of interest based on numerical thresholds applied to the aforementioned maps. Computation of mismatch between extracted volumes is automatically provided.

The device is intended to be used by trained professionals with medical imaging education including but not limited to, physicians and medical technicians in the imaging assessment workflow by extraction and communication of metrics from CT Perfusion dataset.

The results of CT Perfusion V1.0 are intended to be used in conjunction with other patient information and, based on professional judgment, to assist the clinician in the medical imaging assessment. Trained professionals are responsible for viewing the full set of native images per the standard of care.

The device does not alter the original image. CT Perfusion V1.0 is not intended to be used as a standalone diagnostic device and shall not be used to take decisions with diagnosis or therapeutic purposes. Patient management decisions should not solely be based on CT Perfusion V1.0 results.

CT Perfusion V1.0 can be integrated and deployed through technical platforms, responsible for transferring, storing, converting formats, notifying of detected image variations and display DICOM of imaging data.

Device Description

Introduction

The CT perfusion V1.0 application can be used to automatically compute qualitative as well as quantitative perfusion maps based on the dynamic (first-pass) effect of a contrast agent (CA). The perfusion application assumes that the input data describes a well-defined and transient signal response following rapid administration of a contrast agent.

Olea Medical proposes CT Perfusion V1.0 as an image processing application, Picture Archiving Communications System (PACS) software module that is intended for use in a technical environment, which incorporates a Medical Image Communications Device (MICD) (21 CFR 892.2020) as its technical platform.

CT Perfusion V1.0 interaction with the technical platform

For optimal performance, the docker needs a technical base (MICD). The technical platform allows the docker to:

- receive the inputs;
- provide the outputs;
- visualize the outputs as the docker has no interface.

The technical base can support several applications encapsuled in a docker such as CT Perfusion V1.0.

Principles of operation and technological characteristics of CT Perfusion V1.0

CT Perfusion V1.0 image processing application is designed as a docker installed on a technical platform, a Medical Image Communications Device.

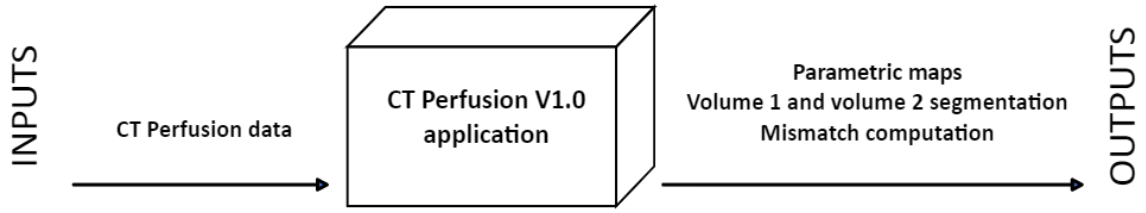

Figure 1: CT Perfusion V1.0 inputs/outputs

CT Perfusion V1.0 is a docker totally independent from the technical platform in which it is integrated:

- Input DICOM images are received by the technical platform;
- Relevant series are automatically identified among the images received in the platform by reading the relevant DICOM tags and are provided to the application;
- The arrival of identified series will launch CT Perfusion V1.0;
- The CT Perfusion V1.0 processes the identified series;
- The generated results are automatically pushed to the technical platform;
- The results can be visualized with any DICOM viewer comprising but not limited to the technical platform or exported to a dedicated file location.

The CT Perfusion V1.0 application takes as input a full CT perfusion (CTP) sequence acquired following the injection of an iodine contrast agent.

By processing these input image series, the application provides the following outputs:

- Parametric maps.
- Volume 1 and volume 2 segmentation in DICOM format. Fusion of segmented Volume 1 and 2 and CTP map could be provided in PNG and DICOM secondary captures.
- Mismatch computation:
    - Mismatch volume = Volume 2-Volume 1
    - Mismatch ratio = Volume 2/Volume 1
    - Relative Mismatch = (Volume 2-Volume 1)/Volume 2*100.

CT Perfusion V1.0 does not contain any AI-based algorithms. All calculations are based on deterministic algorithms.

The CT Perfusion V1.0 offers automatic volume segmentations based on a set of maps and thresholds. The user is able to tune/adjust these thresholds and the maps associated to thresholds in the configuration files.

Substantial Equivalence

The following Predicate Device Comparison Table provides a summary of the comparison between the CT Perfusion V1.0 and its predicate device.

CT Perfusion V1.0	Olea Sphere® V3.0 (K152602)
Parametric maps computation	YES
Hypoperfused areas segmentations on maps (e.g : CBF and TTP)	YES
Mismatch computation	YES

To explain that the subject device and the predicate device are comparable, it is important to point out that CT Perfusion V1.0 represents a subset of functionality of Olea Sphere V3.0. Comparative performance testing was conducted using the comparable Perfusion module in Olea Sphere V3.0.

Both CT Perfusion V1.0 and Olea Sphere® V3.0 are user-defined software analysis tools used for the analysis of CT studies.

Both devices are intended for use in hospitals and imaging centers. Importantly, neither software product is used for diagnosis. Patient management decisions should not be based solely on the results of either software. Therefore, the intended use of the software is the same.

Both the CT Perfusion V1.0 and Olea Sphere V3.0 have similar technological characteristics as they both:

- provide processing capabilities for the analysis of CT series;
- are designed to be able to process CT series;
- are able to provide same outputs;
- are able to automatically compute the mismatch between extracted volumes.

CT Perfusion V1.0 and Olea Sphere V3.0 have essentially equivalent features. The only difference is that Olea Sphere V3.0 is equipped with a visualization interface whereas CT Perfusion V1.0 needs to communicate with a technical platform to visualize the outputs.

This minor difference does not impact the intended use of the device or raise different questions of safety and efficacy.

Performance Data

Olea Medical has conducted extensive validation testing of the CT Perfusion V1.0. Internal verification and validation testing confirm that the product specifications are met and supports substantial equivalence of the intended use and technological characteristics to the predicate device.

CT Perfusion V1.0 has been validated to ensure that the system as a whole provides all the capabilities necessary to operate according to its intended use and in a manner substantially equivalent to the predicate device.

The following performance evaluations were conducted:

- Product risk assessment;
- Software modules verification tests;
- Software validation test;
- Clinical image comparison study.

Based on the performance as documented in the clinical image comparison study, the CT Perfusion V1.0 has a safety and effectiveness profile that is similar to the predicate device. Indeed:

- Parametric maps result comparison: All parametric maps (CBF, CBV, MTT, TTP, Delay, tMIP) computed with CT Perfusion V1.0 and Olea Sphere® V3.0 predicate device were identical: value differences voxel-by-voxel were equal to zero; Pearson and Spearman correlation coefficients were equal to 1.

- Volumes result comparison: Mean DICE index (similarity coefficient) was equal to 1 between CT Perfusion V1.0 and Olea Sphere® V3.0 predicate device segmentations. It could be concluded that volume shape and position were identical. For all cases, no difference was found as the volumes derived from both thresholds were similar between CT Perfusion V1.0 and Olea Sphere® V3.0 predicate device.

Conclusions

CT Perfusion V1.0 is substantially equivalent to the predicate device, Olea Sphere® V3.0. The CT Perfusion V1.0 has the same intended use and similar indications for use, technological characteristics, and principles of operation as its predicate device.

In addition, the minor technological differences between the CT Perfusion V1.0 and its predicate devices raise no new questions of safety or effectiveness. Performance data demonstrate that the CT Perfusion V1.0 is as safe and effective as the Olea Sphere® V3.0. Thus, the CT Perfusion V1.0 is substantially equivalent.