December 17, 2021

Dyad Medical, Inc.
Rory Carrillo
Quality & Regulatory
215 Brighton Avenue, Suite 203
Boston, Massachusetts 02134

Re: K210931
Trade/Device Name: Libby IAAA v1.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: November 12, 2021
Received: November 18, 2021

Dear Rory Carrillo:

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,

Aneesh Deoras
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210931

Device Name
Libby IAAA v1.0

Indications for Use *(Describe)*
Libby IAAA is intended to review and analyze Intravascular optical coherence tomography (OCT) images in raw OCT file format. IAAA enables quantification of artery and/or stent dimensions. The software is intended to be used by or under supervision of a Cardiologist.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

1. General Information

510(k) Sponsor	Dyad Medical, Inc.
Address	215 Brighton Avenue, Suite 203 Boston, MA 02134
Correspondence Person	Rory A. Carrillo Quality and Regulatory Consultant RAC Medical Consulting, LLC
Contact Information	Email: rory@cosmhq.com Phone: 562-533-7010
Date Prepared	March 29, 2021

2. Proposed Device

Proprietary Name	Libby IAAA v1.0
Premarket Notification	K210931
Common Name	Libby IAAA
Classification Name	System, Image Processing, Radiological
Regulation Number	21 CFR 892.2050
Regulation Name	Picture archiving and communication system
Product Code	LLZ
Regulatory Class	II

3. Predicate Device

Proprietary Name	*Pie Medical CAAS Intravascular*
Premarket Notification	K123970
Classification Name	System, Image Processing, Radiological
Regulation Number	21 CFR 892.2050
Regulation Name	Picture archiving and communications system
Product Code	LLZ
Regulatory Class	II

4. Device Description

The Libby IAAA v1.0 platform is a web-accessible post-processing analysis device used for viewing and quantifying intravascular OCT images. The device is intended to visualize and quantify OCT pullback data in raw OCT file format. The device enables lumen, stent, and stent strut detection and has features for loading, saving, and report generation of aggregated

quantitative data. The device allows for analysis of raw Intravascular optical coherence tomography (OCT) files obtained from the Abbott Laboratories C7-XR system and compatible imaging catheters.

The web-based platform can be used in common desktop web browsers. A user opens an intravascular image pullback file using the platform and has the ability to use various modules to perform image analysis on areas of interest. The platform includes the following module panels for visualization, quantification, and report generation:

Visualization:

- 2D cross-sectional view
- 2D longitudinal view
- Image navigation tools
- Measurement and annotation tools
- Bookmark areas of interest

Quantification:

- Distance and area measurements
- Guidewire detection
- Lumen and Stent area quantification
- Stent and strut detection (pullback level and frame level)
- Strut classification (covered versus uncovered, apposed, and malapposed)

Data Reporting:
Study information, lumen areas, stent areas, reference areas, percent stenosis, along with user-created annotations are displayed to the user within the software. The software automatically saves all data and the user has the option to generate a report in .xlsx format.

The product is intended to be used by or under supervision of a board-certified Cardiologist.

5. Intended Use

Libby IAAA is intended to review and analyze Intravascular optical coherence tomography (OCT) images in raw OCT file format. IAAA enables quantification of artery and/or stent dimensions. The software is intended to be used by or under supervision of a Cardiologist.

6. Substantial Equivalence

Feature/ Function	Proposed Device: Libby IAAA v1.0 (K210931)	Predicate Device: *Pie Medical CAAS Intravascular* (K123970)
Intended Use & Indications for Use	Libby IAAA is intended to review and analyze Intravascular optical coherence tomography (OCT) images in raw OCT file format. IAAA enables quantification of artery and/or stent dimensions. The software is intended to be used by or under supervision of a Cardiologist.	CAAS IntraVascular has been developed to review and analyze intravascular images. The software is used by or under supervision of a cardiologist or radiologist. Based on intravascular ultrasound (IVUS) and/or optical coherence tomography (OCT) images CAAS IntraVascular enables quantification of artery and/or stent dimensions.
Intended Users	The software is used by or under supervision of a Cardiologist.	The software is used by or under supervision of a cardiologist or radiologist.
Intended Environment	Healthcare facilities such as hospitals and clinics	Healthcare facilities such as hospitals and clinics
Device Class	II	II
Data Type	Raw OCT data	IVUS and OCT data in DICOM format (vendor independent)
Import of Patient Data	-Manual through keyboard -Automatic import with image file -Study List creation	-Manual through keyboard -Automatic import with image file -Study List creation
Image Display	- 2D OCT reconstruction - Cross-sectional views - Longitudinal reconstruction	-3D OCT reconstruction - Cross-sectional views - Longitudinal reconstruction
Contour Definition	Lumen and stent contour -Automatic -Manual	Lumen, EEM and stent contour -Automatic -Manual
Vessel Analysis	- Stenosis analysis - Stent analysis	- Stenosis analysis - Plaque analysis - Stent analysis

Image Assessment	- Linear (length and diameter), angular and ROI measurements - Volume measurements	- Linear (length and diameter), angular and ROI measurements - Volume measurements
Storage of Results	- Digital report (.xlsx)	-Printout -Reanalysis -Digital PDF report -XML export -DICOM PDF report
Operating System	Web Browser	MS Windows

7. Performance Data

Safety and performance of the Libby IAAA v1.0 has been evaluated and verified in accordance with software specifications, applicable performance standards through software verification and validation testing, and a standalone performance test. Standalone performance testing consisted of a head to head analysis of a generalized dataset manually analyzed by expert cardiologists and compared to the performance of the Libby IAAA algorithm. The software system testing activities were performed in accordance with ANSI/AAMI/*IEC 62304:2006/A1:2016 - Medical device software – Software life cycle processes,* in addition to the FDA Guidance documents, *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"* and *"Content of Premarket Submission for Management of Cybersecurity in Medical Devices."*

8. Conclusion

Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics and performance testing, the Libby IAAA v1.0 raises no different questions of safety and effectiveness and is substantially equivalent to the predicate device in terms of safety, effectiveness, and performance.