AI Medical AG
% Christian Federau
CEO
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SWITZERLAND

September 22, 2023

Re: K223659
Trade/Device Name: Jazz
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: August 22, 2023
Received: August 25, 2023

Dear Christian Federau:

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 Radiological 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)*
K223659

Device Name
Jazz

Indications for Use *(Describe)*
Jazz is intended for the labeling, visualization and volumetric quantification of segmentable brain structures from a set of MR images, for patients with a known diagnosis of multiple sclerosis (for the multiple sclerosis pipeline) and/or brain metastasis (for the metastasis pipeline), and the production of a radiological report.

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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K223659
510(k) Summary

5.1 Submitter

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Date prepared	15 Aug 2023

5.2 Device

Device Trade Name	Jazz
Common Name	Medical Image Processing Software
Classification Name	System, Image processing, Radiological
Number	892.2050
Product Code	QIH (LLZ)
Classification Panel	Radiology

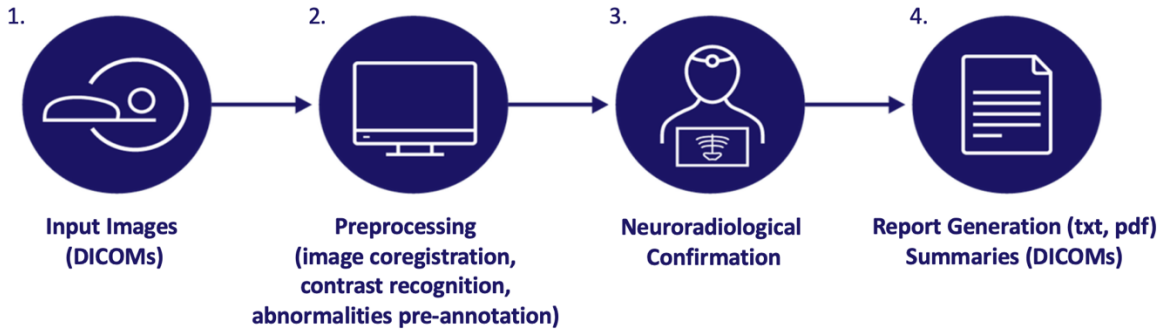
5.3 Predicate Device

510(k) Number	K192130
Device Name	icobrain
Manufacturer	icometrix NV Tervuursesteenweg 244 B-3001 Leuven Belgium
Classification Name	System, Image processing, Radiological
Number	892.2050
Product Code	LLZ
Classification Panel	Radiology

5.4 Device Description

Jazz is a Software as a Medical Device (SaMD) consisting of a software intended to be a facilitating tool for the physicians, in the sense of a semi-automatic pipeline for the process of identifying, labeling and quantifying the volume of segmentable brain structures identified on MR images. “Semi-automatic” refers to the possibility given to the physician to correct the segmentation of the software before saving.

The following flowchart illustrates the overall architecture of Jazz.



The input images must be MR images. During pre-processing, images get coregistered, contrast get recognized, and the abnormalities can get optionally pre-annotated. Several algorithms for the pre-annotation of the abnormalities can be used during the preprocessing. In case a pre-annotation get used, the physician can evaluate the pre-annotation of the different algorithms, and select the one he judges the best. He might also decide to use none of them. In all cases, the physician has to review the annotation.

In other words, the use of a pre-annotation of the abnormalities by the physician is facultative, and he has the choice to:

1. use a pre-annotation of abnormalities as they are, if he considers it is adequate after reviewing them
2. use a pre-annotation of abnormalities but correct them, if he considers that corrections are necessary adequate after reviewing them
3. don’t use a pre-annotation of abnormalities at all, and annotate the anomalities manually himself

Finally, the physician output is used to compute an electronic report, which again can be annotated by the physician if he considers it necessary. The electronic report and images summaries get saved in the format choosen by the user (txt, pdf, DICOMs). Thus, the physician remains fully in control of the output.

5.5 Indication of Use

Jazz is intended for the labeling, visualization and volumetric quantification of segmentable brain structures from a set of MR images, for patients with a known diagnosis of multiple sclerosis (for the multiple sclerosis pipeline) and/or brain metastasis (for the metastasis pipeline), and the production of a radiological report.

5.6 Comparison of Technological Characteristics with the Predicate Device

Jazz, the device subject to this submission and IcoBrain, the predicate device (K192130) have an identical classification.

Device	Jazz	IcoBrain
Regulation Number	21 CFR 892.2050	21 CFR 892.2050
Device Classification Name	System, Image processing, Radiological	System, Image processing, Radiological
Product Code	QIH (LLZ)	LLZ
Regulatory Class	II	II
Intended Use / Indications for use	Jazz is intended for the labeling, visualization and volumetric quantification of segmentable brain structures from a set of MR images, for patients with a known diagnosis of multiple sclerosis (for the multiple sclerosis pipeline) and/or brain metastasis (for the metastasis pipeline), and the production of a radiological report.	icobrain is intended for automatic labeling, visualization and volumetric quantification of segmentable brain structures from a set of MR or NCCT images. This software is intended to automate the current manual process of identifying, labeling and quantifying the volume of segmentable brain structures identified on MR or NCCT images. icobrain consists of two distinct image processing pipelines: icobrain cross and icobrain long. • icobrain cross is intended to provide volumes from MR or NCCT images acquired at a single time point. • icobrain long is intended to provide changes in volumes between two MR images that were acquired on the same scanner, with the same image acquisition protocol and with same contrast at two different timepoints. The results of icobrain cross cannot be compared with the results of icobrain long.

Table 1. Comparison with predicate device

Device and predicate device are software for identifying and quantifying the volumes of brain structures, labeling and visualization. Both devices take 3D MR images of the brain as input and generate an electronic report with similar quantitative information.

Both devices are DICOM compatible, operate on off-the-shelf hardware and are used by trained professionals in hospitals, imaging centers or in image processing labs.

The Jazz software includes a verification and correction step by a trained physician before the report is produced. Icobrain produces the report automatically.

5.7 Performance Data

To demonstrate the performance of Jazz, the measured volumes of the segmentable brain structures are validated for accuracy and reproducibility. In the accuracy experiments, the measured volumes are validated for accuracy against manually labeled ground truth volumes. In the reproducibility experiments, the volumes are compared on test-retest image data sets. A literature review has been performed to set relevant acceptance criteria for each type of experiment. All experiments passed the acceptance criteria.

This device uses machine learning algorithms as part of its key functionality. Networks were trained using brain images, which were fully segregated from the test set, and using a ground truth which was set using gold standard human expert opinion.

The experiments encompassed 344 subject datasets in total. The subjects upon whom the device was tested include healthy subjects, multiple sclerosis and metastasis patients.

In one accuracy experiment, the acceptance criteria for device performance were set to be a voxel-wise sensitivity of at least 40%, a voxel-wise specificity of at least 95%, and a lesion-wise dice score of at least 0.5 for both the multiple sclerosis high sensitivity and high specificity models, as well as a lesion-wise true positive rate of at least 60% and a lesion-wise false negative rate of at most 40% for the high sensitivity model, as well as a lesion-wise false discovery rate of at most 50% for the high specificity model.

In another accuracy experiment, the accuracy of the anatomy localization was assessed using an anatomy localization score, and the acceptance criteria for device performance was set to an anatomy localization score of 1 (best) in at least 80% of the cases, and an anatomy localization score of 6 in less than 10% of the lesions.

In another accuracy experiment, the accuracy of the coregistration was assessed using a coregistration score, and the acceptance criteria for device performance was set to an average quality of the coregistration score larger than 4 (good coregistration), and the percentage of the coregistration score equaling 2 (bad coregistration) or worse smaller than 10%.

Reproducibility was tested by producing and reproducing a report using Jazz. The acceptable device performance were set to be an identical number of lesions, total lesions volume and report generated in a process-reprocess experiment with Jazz.

All experiments passed the acceptance criteria. In addition, system verification tests demonstrated that the system provides the capabilities necessary to operate according to its intended use.

5.8 Conclusions

Jazz is a labeling, visualization and segmentation software which has similar intended use and indications for use statement as the predicate device. This 510(k) submission includes information on Jazz technological characteristics, as well as performance data and verification and validation activities demonstrating that Jazz is as safe and effective as the predicate, and does not raise different questions of safety and effectiveness.

Declarations:	• This summary includes only information that is also covered in the body of the 510(k). • This summary does not contain any puffery or unsubstantiated labeling claims. • This summary does not contain any raw data, i.e., contains only summary data. • This summary does not contain any trade secret or confidential commercial information. • This summary does not contain any patient identification information.

This document is reviewed and approved by Christian Federau, CEO of AI Medical, based on the present data and information.