Motilent Ltd.
℅ Ian Knott
Head of Regulatory and Quality
IDEALondon, 69 Wilson Street
London, EC2A 2BB
UNITED KINGDOM

November 8, 2021

Re: K211356
Trade/Device Name: GIQuant
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: September 7, 2021
Received: October 7, 2021

Dear Ian Knott:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*
K211356

Device Name
GIQuant

Indications for Use *(Describe)*
GIQuant is a post-processing software integrated into existing medical imaging workflows that is intended to derive motion related parameters from abdominal data obtained during magnetic resonance imaging (MRI).

GIQuant is designed to aid trained physicians in advanced image assessment, treatment consideration, and monitoring of therapeutic response. The information provided by GIQuant should not be used in isolation when making patient management decisions.

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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"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."

Document Title:	**5.0 GIQuant 510k - 510k summary**

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

1. Submitter:

Motilent Ltd.
IDEALondon,
69 Wilson Street,
London,
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United Kingdom

Contact Person: Ian Knott
Submitter, Holder and Owner
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E-mail: Ian.Knott@motilent.co.uk

Date Summary Prepared: April 12, 2021

2. Device:

Device Name:	GIQuant
Device Common Name:	Radiological Image Processing Software
Regulation Number:	21 CFR 892.2050
Regulation name:	Medical image management and processing system
Device Classification:	Class II
Product code:	LLZ

3. Predicate Device Information:

GIQuant is substantially equivalent to the following legally marketed devices that are currently cleared by the FDA:

510(k) reference	Device Name	Manufacturer	Clearance date
K123302	IB Clinic v1.0 (clinic)	Imaging Biometrics, LLC	11 January 2013

4. Device Description:

GIQuant is a standalone software medical imaging post processing application that runs on standard computer hardware. GIQuant performs numerical analysis and generates image parameter maps, based on DICOM images captured via Magnetic Resonance Imaging.

These actions include:

- Receipt of MR DICOM image studies from DICOM storage and communication devices.
- Registration of images generated at different time points.
- Comparison of registered images.
- Computation of motility parameter maps based on dynamic abdominal MR imaging data.
- Output of the above maps in DICOM format for export to PACS.

GIQuant can be deployed within its own image storage and communication infrastructure or alternatively it can be "plugged in" and launched from within other FDA cleared applications.

5. Indications for Use:

GIQuant is a post-processing software integrated into existing medical imaging workflows that is intended to derive motion related parameters from abdominal data obtained during magnetic resonance imaging (MRI).

GIQuant is designed to aid trained physicians in advanced image assessment, treatment consideration, and monitoring of therapeutic response. The information provided by GIQuant should not be used in isolation when making patient management decisions.

6. Comparison of Technological Characteristics with the predicate device

The intended use and performance characteristics for the subject device are substantially equivalent to the predicate device listed in section 3 above as both devices are intended for image analysis, image processing and generation of parametric maps to provide additional information beyond standard imaging.

A table comparing the key features of the subject and predicate device is provided below.

	Subject Device	Predicate device
Device Name	GIQuant	IB Clinic v1.0 (clinic)
510(k) Clearance number	N/A	K123302
Common Name	Radiological Image Processing Software	Radiological Image Processing Software
Regulation Number:	892.2050	892.2050
Regulation Name	Medical image management and processing system	Medical image management and processing system
Product code	LLZ	LLZ
Indications for use:	GIQuant is a post-processing software integrated into existing medical imaging workflows that is intended to derive motion related parameters from abdominal data	IB Clinic v1.0 (Clinic) is a post-processing software toolkit designed to be integrated into existing medical image visualization applications running on standard computer hardware. Clinic accepts relevant DICOM

	obtained during magnetic resonance imaging (MRI). GIQuant is designed to aid trained physicians in advanced image assessment, treatment consideration, and monitoring of therapeutic response. The information provided by GIQuant should not be used in isolation when making patient management decisions.	image sets, such as dynamic perfusion and diffusion image sets. Clinic generates various perfusion- and diffusion-related parameters, standardized image sets, and image intensity differences. The results are saved to a DICOM image file and may be further visualized on an imaging workstation. Clinic is designed to aid trained physicians in advanced image assessment, treatment consideration, and monitoring of therapeutic response. The information provided by Clinic should not be used in isolation when making patient management decisions.
Standalone Software	Yes	Yes
Energy Sources	N/A	N/A
Operates on off-the-shelf hardware	Yes	Yes
Standard windowing user interface	yes	yes
Post processing	yes	yes
Conforms to DICOM standards (PS 3.10)	yes	yes
Input data - Processes MR data	Yes	Yes
Input data - Abdominal Imaging	Yes	Yes
Input data - Imaging Modality	MR	MR and CT
Input data - Compatible MRI systems	All approved MRI systems generating DICOM compliant images	All approved MRI systems generating DICOM compliant images
Input data - Imaging Acquisition Protocol*	Dynamic 'cine' MR imaging, combination of T1 and T2 weighted images	Dynamic T1 and T2 weighted images
Input data - *Data format*	DICOM	DICOM
Transformation - Segmentation	Whole image registration	Whole image registration
Transformation – Registration	Non-rigid registration to align image features in time series data Registration of 2d image data Registration applied on raw image data	Non-rigid registration to align image features in time series data Registration of 2d image data Registration applied on raw image data
Transformation – Parameterization*	Derived from image registration deformation fields represented as the SD Jacobian	Derived from variations in intensity over time
Output data -Results generation	Parametric map	Parametric map
Output data -*Spatial localisation*	1:1 anatomical mapping	1:1 anatomical mapping
Output data -*File format*	DICOM	DICOM
Output data -*Summary metrics*	Summary metrics can be obtained to quantify movement within a region of interest	Summary metrics can be obtained to quantify changes in intensity over time within a region of interest
Output data- Networking	Exported to PACS and/or OS file storage	Exported to PACS and/or OS file storage
Reporting - Intended user	Result interpreted by trained user (e.g Radiologist)	Result interpreted by trained user (e.g Radiologist)
Reporting - Viewing	Results can be viewed on DICOM compatible PACS viewer	Results can be viewed on DICOM compatible PACS viewer
Reporting - Availability of data	Original data available for viewing with output	Original data available for viewing with output

*As evidenced from the table above, the subject and predicate device share the same core technological functionality however minor differences exist between the two devices under review. These differences are not considered to raise different questions with relation to safety and effectiveness and have been evaluated through performance testing.

7. Performance Data:

Software verification and validation testing has been conducted and documentation provided as per the recommendations of FDA guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May, 2005).

The software was developed in compliance with the requirements of IEC 62304:2006, ISO 14971:2019, and NEMA PS 3.1-3.20 (2016).

Software verification testing
Software verification testing was conducted at a unit, integration and systems level to verify the implementation of functional requirements.

Technical Performance testing
Technical performance assessment established the performance and suitability of GIQuant's algorithm in the context of shared questions with relation to safety and effectiveness. Methods utilized in performance testing included utilizing summary metrics obtained through region of interest placement on synthetically manipulated 'ground truth' datasets as well as measuring target registration error on a fixed point of anatomy when a region of interest propagated through a dataset is corrected by an expert user. Reproducibility was established through test-retest image data sets.

Validation Testing
Software Validation testing was conducted to confirm the implementation of functional requirements within the context of a simulated real world use environment.

The tests results demonstrate that GIQuant functioned as intended, is acceptable for clinical use, and is safe and effective as its predicate device, without introducing new questions of safety and efficacy.

8. Conclusion:

GIQuant shares the same intended use as the cited predicate device. Verification and validation testing performed demonstrates that GIQuant performs as intended in the context of the specified use condition. Technical performance data shows that, where technological differences are apparent, GIQuant performs to a suitable level to address shared questions with relation to safety and effectiveness. It can therefore be concluded that GIQuant is substantially equivalent to the predicate device.

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 labelling 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.