Q Bio, Inc.
M. Jason Brooke
MSE, JD, CSQE, Brooke & Associates
1411 Industrial Road
San Carlos, California 94070

September 12, 2024

Re: K241280
Trade/Device Name: Constellation (CON-001)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH, LLZ, LNH
Dated: August 15, 2024
Received: August 15, 2024

Dear M. Jason Brooke:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Jessica Lamb, Ph.D.
Assistant Director
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241280

Device Name

Constellation (CON-001)

Indications for Use *(Describe)*

Constellation is intended for non-invasive labeling and calculation of quantitative measurements for anatomical regions. Constellation utilizes DICOM MR images gathered on a GE MR450W that encompass the whole-body. It is intended to be used for healthy adult patients. Clinicians may use Constellation as a clinical decision support tool, but it is not to be used in triage events, emergency medicine, or critical care. A clinician retains the ultimate responsibility for making the pertinent diagnosis based on their standard practices.

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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Q Bio, Inc.
1411 Industrial Road
San Carlos, CA 94070 USA

510(k) Summary

(Information provided in conformance with 21 CFR 807.92)

510(k) Submitter:	Q Bio, Inc. 1411 Industrial Road San Carlos, CA 94070 USA.
Contact Person:	M. Jason Brooke, MSE, JD, CSQE Brooke & Associates Email: jbrooke@devicecounsel.com Phone: +1 202-258-1422
Additional Correspondents:	Clarissa Shen Chief Operating Officer Email: clarissa.shen@q.bio Phone: +1 415-967-7622
Date Summary Prepared	April 26, 2024
Trade Name:	Constellation
Common Name:	Automated radiological image processing software
Classification:	Class II
Regulation Number:	21 CFR 892.2050
Product Code:	QIH - Automated Radiological Image Processing Software LLZ - System, Image Processing, Radiological
Review Panel:	Radiology

Predicate Devices:

Primary Predicate:	Secondary Predicate:
Manufacturer: CorticoMetrics, LLC	Manufacturer: AMRA Medical AB
Trade Name: THINQ	Trade Name: AMRA Profiler
510(k) Number: K192051	510(k) Number: K211983
Product Code: LLZ	Product Code: LNH

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1. Device Description

Constellation is an automated image post-processing software application used in a clinical MRI setting. Constellation combines MR images from overlapping anatomical stations to segment anatomical regions and provide associated quantitative measurements for whole-body patient anatomy. These anatomical regions include the lower limb muscles, visceral adipose tissue, subcutaneous adipose tissue, kidneys, liver, spleen, lungs, and brain structures. A PDF report contains quantified measurements alongside a whole-body visualization and segmented label images.

Constellation provides alpha-blending of the anatomical image with the corresponding labels in the final report. This process combines one stitched output (background) with another (foreground) to create a final anatomical label with both grayscale and color resulting from the blending of the background (greyscale) and foreground label.

Constellation is a tool intended to assist trained physicians in the assessment of MR images of the whole body. The software is not designed to provide any automated detection or diagnosis. Physicians retain the ultimate responsibility for making any diagnosis from the presented images based on their standard practices and patient background, clinical history, symptoms, and other diagnostic information.

2. Intended Use

Constellation is a software application that stitches together MR images, automatically labels, and calculates quantitative measurements for anatomical regions. The device outputs are designed to be used by clinicians as a clinical decision support tool and are not to be used in triage events, emergency medicine, or critical care. It is not intended to be a sole source of medical diagnosis. A clinician retains the ultimate responsibility for making the pertinent diagnosis based on their standard practices.

3. Indications for Use

Constellation is intended for non-invasive labeling and calculation of quantitative measurements for anatomical regions. Constellation utilizes DICOM MR images gathered on a GE MR450W that encompass the whole-body. It is intended to be used for healthy adult patients. Clinicians may use Constellation as a clinical decision support tool, but it is not to be used in triage events, emergency medicine, or critical care. A clinician retains the ultimate responsibility for making the pertinent diagnosis based on their standard practices.

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4. Summary of Technological Characteristics Comparison

A summary of the comparison between technological characteristics of Constellation and its predicate devices is provided in Table 1 below.

Table 1: Summary of Technological Characteristics Comparison

	Q Bio, Inc. (Subject Device)	**CorticoMetrics LLC (Primary Predicate)**	**AMRA Medical AB (Secondary Predicate)**	**Differences**
Product Name	Constellation	THINQ	AMRA Profiler	N/A
510(k) Number	K241280	K192051	K211983	N/A
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.1000	Same as primary predicate
Regulation Description	Medical Image Management and Processing System	Medical Image Management and Processing System	Magnetic Resonance Diagnostic System	Same as primary predicate
Classification Name	System, Image Processing, Radiological	System, Image Processing, Radiological	System, Nuclear Magnetic Resonance Imaging	Same as primary predicate
Classification	II	II	II	Same
Product Code	QIH, LLZ	LLZ	LNH	Similar to predicate
Indications for Use	Constellation is intended for non-invasive labeling and calculation of quantitative measurements for anatomical regions. Constellation utilizes DICOM MR images gathered on a GE MR450W that encompass the whole-body. It is	THINQ is intended for automatic labeling, visualization and volumetric quantification of segmentable brain structures from a set of MR images. Volumetric measurements	Indicated for use as a magnetic resonance diagnostic device software application for non-invasive fat and muscle evaluation that enables the generation, display and review of 2D	Same

	Q Bio, Inc. (Subject Device)	CorticoMetrics LLC (Primary Predicate)	AMRA Medical AB (Secondary Predicate)	Differences
	intended to be used for healthy adult patients. Clinicians may use Constellation as a clinical decision support tool, but it is not to be used in triage events, emergency medicine, or critical care. A clinician retains the ultimate responsibility for making the pertinent diagnosis based on their standard practices.	may be compared to reference percentile data.	magnetic resonance medical image data. Designed to utilize DICOM 3.0 compliant magnetic resonance image datasets, acquired from compatible MR Systems, to display the internal structure of the body including the liver. Other physical parameters derived from the images may also be produced. Provides a number of quantification tools, such as Region of Interest (ROI) placements, to be used for the assessment of regions of an image to quantify liver tissue characteristics, including the determination of fat fraction in the liver, T2, and muscle volume. These images and the physical parameters derived from the images, when interpreted by a trained clinician, yield information that may assist in diagnosis.	
User	Clinicians	Medical professionals	Medical professionals	Similar
Hosting platform	Internal server	On-site hosting or internal server	Internal server	Same

	Q Bio, Inc. (Subject Device)	**CorticoMetrics LLC (Primary Predicate)**	**AMRA Medical AB (Secondary Predicate)**	**Differences**
Image Modality	MR	MR	MR	Same
Design				
Operating System	Mac	Linux	Linux	Similar
Physical Characteristics	Software package. Operates on off-the-shelf hardware (Apple)	Software package. Operates on off-the-shelf hardware (multiple vendors)	Software package	Same
Technology	Non-AI based Algorithms (brain, lungs, femur, lower limb muscles, SAT) Convolutional neural networks (kidneys, spleen, liver, VAT)	Non-AI based Algorithms	Non-AI based Algorithms	Similar
Safety	• Automated quality control functions: - Scan protocol verification - Accurate patient coordinate system encoding - Image quality threshold checks • Results are reviewed by a trained quality assurance team and a clinician	• Automated quality control functions: - Scan sequence (protocol) checks - Atlas alignment checks - Cortical surface checks - Result validity checks • Results must be reviewed by a trained clinician	• Image quality issues are described and presented in the report • Automatic sequence protocol conformance check	Same
Features				

	Q Bio, Inc. (Subject Device)	**CorticoMetrics LLC (Primary Predicate)**	**AMRA Medical AB (Secondary Predicate)**	**Differences**
Anatomical Area of Interest	Head and Whole Body	Head	Whole Body	Same
Alpha-Blended Color Images	Yes	Yes	Yes	Same
User Access Point	Post-processing application	Post-processing application	Post-processing application	Same
Image Input	DICOM	DICOM	DICOM	Same
Intensity Normalization	Equalize station intensity: optional	Equalize station intensity: Yes	Equalize station intensity: Yes	Similar
Registration	Atlas based registration for segmentation of brain regions and leg muscles.	Automatic registration of brain segmentation atlas to the input image.	Registration for leg muscle segmentation.	Similar
Acquisition plane	Axial, Sagittal	Sagittal	Axial	Same
Sequence compatibility	T1 MPRAGE, 2-point DIXON, 6-point DIXON	T1 MPRAGE	2-point DIXON, 6-point DIXON	Same
Output	• PDF report with quantitative measurements including	• PDF report with volumetric measurements	• PDF report with volumetric measurements	Same

	Q Bio, Inc. (Subject Device)	**CorticoMetrics LLC (Primary Predicate)**	**AMRA Medical AB (Secondary Predicate)**	**Differences**
	organ, muscle, and fat volumes ● Includes segmented color overlays and structures	● Includes segmented color overlays and structures ● Automatically compares results to reference percentile data ● DICOM images with segmentation overlays	● Body composition profile measurements: subcutaneous and visceral fat volume, muscle fat, muscle volume and liver fat	
Export Format	PDF	PDF and DICOM images	PDF	Same

5. Performance Testing

The following clinical and non-clinical tests were performed to evaluate Constellation's performance:

- Segmentation accuracy of the lungs, liver, spleen, kidneys, muscle, and fat (visceral and subcutaneous) is evaluated using the Dice Similarity Coefficient (DSC) and mean percent absolute difference as primary and secondary figures of merit (FOM).
- Segmentation accuracy for brain cortical/subcortical regions is evaluated via mean percent absolute difference and Pearson's correlation coefficient as the primary and secondary FOMs.
- Liver Volume of Interest (VOI) placement is evaluated via majority voting of three radiologists.
- Device repeatability is evaluated by calculating the DSC and mean percent absolute difference for the same MRI scans passed twice through Constellation.
- Test-retest measurement repeatability is evaluated using the mean percent absolute difference and Pearson's correlation coefficient as the primary and secondary FOMs.
- Manual segmentations are established as ground-truth via inter-rater and intra-rater variability studies. The variability in manual segmentations will be evaluated via DSC.
- Software verification testing was conducted for Constellation to validate it for its intended use according to recommendations outlined in "General Principles of Software Validation, Guidance for Industry and FDA Staff". The Constellation software demonstrated passing results on all applicable unit, integration, and requirements testing.
- Software usability testing was conducted for Constellation to validate it for its intended use according to the FDA guidance titled: "Applying Human Factors and Usability Engineering to Medical Devices". The Constellation software demonstrated passing results in the applied usability testing.

The test results demonstrated that Constellation performs to its intended use and does not introduce new questions of safety or effectiveness. A full description of the software functionality, device hazard analysis, software requirements, verification, validation, and performance testing is provided in this submission.

6. Conclusions

The performance testing presented shows that Constellation is as safe, as effective, and performs as well as the predicate devices.

Any technological differences between Constellation and its predicate devices do not raise new questions of safety and effectiveness. Therefore, Constellation is substantially equivalent to its predicate devices.