Imbio, LLC
% Vipul Goel
Sr. Manager
807 Broadway Street NE, #350
MINNEAPOLIS MN 55413

March 16, 2018

Re: K180129
Trade/Device Name: Imbio Segmentation Editing Tool Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 11, 2018
Received: January 17, 2018

Dear Vipul Goel:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180129

Device Name
Imbio Segmentation Editing Tool Software

Indications for Use *(Describe)*
The Imbio Segmentation Editing Tool Software is used by trained medical professionals asa tool to modify the contours of segmentation masks produced by Imbio algorithms or to manually create segmentation mask contours. The Segmentation Editing Tool can provide further support to the users of Imbio's algorithms.

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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5.0 510(k) Summary

K180129

Table 3: 510(k) summary

510(k) Summary (As required by Section 21 CFR 807.92(c))	
Submitter:	Imbio LLC 807 Broadway ST NE, #350 Minneapolis MN 55413 USA
Contact Person:	Vipul Goel Sr. Manager, QA/RA Telephone: 612-520-7360 Email: vipulgoel@imbio.com Imbio LLC 807 Broadway ST NE, #350 Minneapolis MN 55413 USA
Date Prepared:	Jan 11, 2018
Trade Name:	Imbio Segmentation Editing Tool Software
Common/Usual Name:	Software Accessory for Radiological Image Processing Device
Classification:	System, Image Processing, Radiological 21 CFR 892.2050 Product Code LLZ, Class II
Product Code:	LLZ, Class II
Manufacturer:	Imbio LLC 807 Broadway ST NE, #350 Minneapolis MN 55413 USA
Establishment Registration:	MD6099829
Predicate Device:	Manufacturer: MIM 5.2 (Brachy) Trade name: MIM Software Inc 510(k) Number: K103576 Date Cleared: 18-Feb-2011

510(k) Summary (As required by Section 21 CFR 807.92(c))	
Device Description	Imbio Segmentation Editing Tool (SET) Software is a segmentation editing tool designed to allow users to optimize segmentations calculated by Imbio's fully-automated suite of algorithms (Each algorithm is a separate Imbio program and either has or will be submitted for regulatory approval independently). Imbio is building a suite of medical image post-processing applications that run automatically after data transfer off the medical imaging scanner. Automatic image segmentation is often an essential step in Imbio's analyses. To date, the automatic segmentation algorithms used in Imbio's applications have been robust, however segmentation failures do occur. The purpose of the Segmentation Editing Tool is to provide customers with a tool to locally correct poor segmentations. Additionally, if the Imbio automatic segmentation fails such that it is unable to produce a result, this tool can be used to semi-manually draw the segmentation required for analysis. SET reads in anatomical images used in an automatic segmentation algorithm and the results of the automated segmentation algorithm (if available). The user is then able to locally correct insufficiencies in the segmentation result, or create a segmentation mask from scratch. The finalized segmentation mask is then pushed back to Imbio's Core Computing Platform and the job is re-processed.
Intended Use	Segmentation Editing Tool Software is intended for use by trained medical professionals including, but not limited to, radiologists, oncologists and medical imaging technologists. It is intended to locally correct errors in the segmentation masks produced by Imbio's automatic segmentation algorithms Additionally, if the Imbio segmentation algorithm is unable to produce a segmentation mask, this tool could be used to semi-manually create a segmentation mask. The application will be accessed most typically from a PACS workstation over a modern Internet browser (e.g. IE>10).

510(k) Summary (As required by Section 21 CFR 807.92(c))	
Summary of Technical Comparisons	The fundamental functional characteristics of SET are very similar to the analogous functions included in MIM 5.2 (Brachy). The primary differences between the proposed and predicate devices are that: • Imbio SET is not a standalone application and can only be used in conjunction with other Imbio algorithms installed on Imbio's platform. • Imbio SET has contour snapping and interpolation features that serve as workflow optimization tools for contouring tasks involving large regions of interest. • Imbio SET has a much more limited set of features than MIM 5.2 (Brachy).
Non-Clinical Testing	Non-clinical testing was done to show validity of SET software. Results can be seen in Software Test Protocol/Report attached in Appendix E/Appendix F
Design Validation	Design validation was performed using the Imbio Segmentation Editing Tool Software in actual and simulated use settings.
Clinical Testing	This technology is not new; therefore, a clinical study was not considered necessary prior to release. Additionally, there was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. Usability testing was completed for this product to ensure proper use of the product by intended users.
Conclusion:	The Imbio Segmentation Editing Tool Software has the same technological characteristics as the predicate device in that it has a similar intended use, same general operating principle. The specific details of the predicate device may vary from those of Imbio Segmentation Editing Tool Software. It has been shown in this 510(k) submission that the differences between the Imbio Segmentation Editing Tool Software and the MIM 5.2 (Brachy) (K103576) do not raise any questions regarding safety and effectiveness. The Imbio Segmentation Editing Tool Software, as designed and manufactured, is substantially equivalent to, and as safe and effective as, the referenced predicate device.