IMAGING BIOMETRICS
Creating the Standard

JAN 1 1 2013

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA I990 and 21 CFR §807.92.

The assigned 510(k) number is: k123302

1. Submitter's Identification:

Imaging Biometrics, LLC
13416 Watertown Plank Road, Suite 260
Elm Grove, WI 53122

Contact Person
Michael Schmainda
Submitter, Holder, and Owner
Phone: (262) 439-8252
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Steve Krueger
Consultant
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Email: steve@makcompliance.com

Date Summary Prepared: October 19th, 2012

2. Name of the Device:

Trade Name:	IB Clinic v1.0 (Clinic)
Classification Name:	Picture Archiving and Communication Systems 21 CFR 892.2050
Classification:	Class II
Product Code:	LLZ
Performance Standards:	None established under Food Drug and Cosmetic Act

3. Common or Usual Name:

Radiological Image Processing Systems

4. Predicate Device Information:

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

510(k)	Trade Name	Manufacturer
K080762	IB Neuro v1.0	Imaging Biometrics
K090546	nordicICE	Nordic Imaging Lab

5. Device Description:

Clinic is a platform independent image processing library which consists of a set of code modules which run on standard computer hardware that computes a variety of numerical analyses, image parameter maps, and other image manipulations based on DICOM images captured via MR and CT modalities. These actions include:

- Retrieval of MR and CT DICOM image studies from PACS and/or OS-based file storage.
- Computation of parameter maps for:
  - DSC perfusion (based on MR and CT studies)
  - ADC diffusion (based on MR studies)
- Image manipulations (of MR and CT studies):
  - Registration of images generated at different time points
  - Standardized scaling of image intensities
  - Comparison of registered and/or standardized images
  - Region of Interest (ROI) selection
  - Generation of ROI datasets in DICOM formats
- Output of the above maps in DICOM format for export to PACS and/or OS file storage
- Generation of reports summarizing the computations performed

The IB Clinic code library can be used within standalone FDA cleared applications or can be "plugged in" and launched from within other FDA cleared applications such as Aycan's OsiriX PRO workstation. They are intended for distribution both in combination and in modular form, with functional subsets geared toward specific types of image analysis and marketed with corresponding names, including IB Neuro, IB Diffusion, and IB Delta Suite.

6. Intended Use:

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 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.

Dynamic Perfusion Analysis – Generates parametric perfusion maps used for visualization of temporal variations in dynamic datasets, showing changes in image intensity over time. These maps may aid in the assessment of the extent and type of perfusion, blood volume and vascular permeability changes.

Dynamic Diffusion Analysis – Generates apparent diffusion coefficient maps used for the visualization of apparent water movement in soft tissue throughout the body on both voxel-by-voxel and sub-voxel bases. These images may aid in the assessment of the extent of diffusion in tissue.

Image Comparison – Generates co-registered image sets. Generates standardized image sets calibrated to an arbitrary scale to facilitate comparisons between independent image sets. Generates voxel-by-voxel maps of the image intensity differences between image sets acquired at different times. Facilitates selection and DICOM export of user-selected regions of interest (ROIs).These processes may enable easier identification of image intensity differences between images and easier selection and processing of ROIs.

7. Substantial Equivalence / Comparison to Predicate Devices:

The intended use and performance characteristics for Clinic are substantially equivalent to the predicate devices listed in section 4 above for image analysis, image processing and generation of parametric maps to provide additional information beyond standard imaging.

8. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Imaging Biometrics used the following quality assurance measures for the development of Clinic:

- Product requirements and requirements review
- Product requirements traceability analysis
- Risk analysis
- Design reviews
- Software design process
- Performance testing (verification)
- Safety testing (verification)
- Product software validation

- Product readiness review and approval

9. Discussion of Clinical Tests Performed:

N/A

10. Conclusions:

Clinic has the same intended use and same characteristics as the predicate devices. Moreover, documentation supplied in this submission demonstrates that any difference in technological characteristics do not raise any new questions of safety or effectiveness. Thus, Clinic is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

January 11, 2013

Mr. Mike Schmainda
IMAGING BIOMETRICS, LLC
13416 Watertown Plank Rd Suite 260
Elm Grove, WI 53122

Re: K123302
Trade/Device Name: IB CLINIC V1.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: II
Product Code: LLZ
Dated: October 19, 2012
Received: October 23, 2012

Dear Mr. Schmainda:

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.

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Sean M. Boyd -S for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K123302**

Device Name: **IB Clinic v1.0**

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Prescription Use ___x____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Sean M. Boyd -S

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K123302