

K080762

EXHIBIT #1

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: _____

MAY 15 2008

1. Submitter's Identification:

Imaging Biometrics, LLC
1035 Katherine Drive
Elm Grove, WI 53122

Contact Person
Michael Schmainda
Phone: (262) 385-1796
Email: mike@imagingbiometrics.com

Date Summary Prepared: 3/4/2008

2. Name of the Device:

Trade Name: IB Neuro™ v1.0

Classification Name: MR Diagnostic Device Accessory: 21 CFR 892.1000
Classification: Class II
Product Code: LNH

Classification Name: Picture Archiving and Communication Systems
21 CFR 892.2050

Classification: Class II
Product Code: LLZ

3. Common or Usual Name:

IB Neuro™ 1.0 / PACS device

4. Predicate Device Information:

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

510(k)	Trade Name	Manufacturer
K073167	BrainStat Software Option for GE Signa MR Scanners	GE Medical Systems 3200 N. Grandview Blvd. W-827 Waukesha, WI 53188
K061429	Dynamic MRI Software Option for C-Scan, E-ScanXQ and E-Scan Opera	ESAOTE S.p.A. Via Siffredi, 58 16153 Genova - Italy
K984224	Perfusion Package for Magnetom Vision and Symphony MR Systems	Siemens Medical Systems, Inc. 186 Wood Avenue South Iselin, NJ 08830

5. Device Description:

IB Neuro™ OsiriX Plugin is software designed to analyze dynamically acquired datasets. Using well-established algorithms, parametric perfusion maps can be generated such as Relative Cerebral Blood Volume (rCBV), Cerebral Blood Flow (CBF), Mean Transit Time (MTT) and Time to Peak (TTP). The strength of our software is its ability to extend the productivity of any existing viewer, CAD workstation or PACS via a platform-independent base library that allows for quick and seamless integration into existing server and workstation applications. It also includes other critical features such as:

- Enables rapid creation of a complete array of critical perfusion parameter maps of rCBV, CBF, MTT, TTP
- Automated correction of contrast agent leakage for rCBV maps
- Automated brain mask generation
- Ability to normalize parameters to normal appearing white matter (NAWM)
- Automated report generation
- View dynamic signal time course on a per-voxel basis
- Interactive Arterial Input Function (AIF) selection
- Automatic export of perfusion parameter maps to DICOM images within the same study

6. Intended Use:

IB Neuro™ software allows the processing and display of dynamically acquired MR datasets to evaluate image intensity variations over time. IB Neuro™ v1.0 plug-in accepts data from existing MRI systems, performs quality control checks

and generates parametric perfusion maps such as Relative Cerebral Blood Volume (rCBV), Cerebral Blood Flow (CBF), Mean Transit Time (MTT) and Time to Peak (TTP) and sends the maps to a PACS for subsequent viewing. These images when interpreted by a trained physician may yield information useful in clinical applications. Our advanced technology is designed to easily and rapidly integrate into existing medical image visualization applications.

7. Substantial Equivalence/ Comparison to Predicate Devices:

The intended use and performance characteristics for IB Neuro™ are substantially equivalent to the predicate devices listed in section 4 above for image analysis and 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:

Performance testing included software validation, verification and testing per FDA's software validation guidance.

9. Discussion of Clinical Tests Performed:

N/A

10. Conclusions:

The IB Neuro™ 1.0 device has a similar intended use and similar 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, the IB Neuro™ device is substantially equivalent to predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2008

Mr. Michael Schmainda
CEO
Imaging Biometrics, LLC
1035 Katherine Dr.
ELM GROVE WI 53122

Re: K080762
Trade/Device Name: IB Neuro™ v1.0
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: March 17, 2008
Received: March 18, 2008

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 such 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); 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.

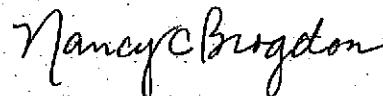
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Exhibit B

Indications for Use

510(k) Number (if known): _____

Device Name: IB Neuro™ v1.0

Indications For Use:

IB Neuro™ software allows the post-processing and display of dynamically acquired MR datasets to evaluate image intensity variations over time. IB Neuro™ v1.0 plug-in accepts data from existing MRI systems, performs quality control checks and generates parametric perfusion maps such as Relative Cerebral Blood Volume (rCBV), Cerebral Blood Flow (CBF), Mean Transit Time (MTT) and Time to Peak (TTP) and sends the maps to a PACS for subsequent viewing. These images when interpreted by a trained physician may yield information useful in clinical applications. Our advanced technology is designed to be compliant with healthcare standards such as DICOM and is easily and rapidly integrated into existing medical image visualization applications.

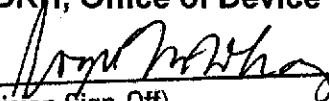
Prescription Use: X
(Per 21 CFR 801 Subpart D)

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 Device Evaluation (ODE)



(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

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