K090296

FEB 19 2009

510K SUMMARY
ATOMLAB 400 AND ATOMLAB 500, MODELS #086-330, 086-335, 086-336, 086-332

The Atomlab 400 and Atomlab 500 Radionuclide Dose Calibrator series from Biodex Medical Systems, Inc. is ETL listed for the Medical Device Safety Standards UL6060101, CAN/CSA C22.2 No.:601-1-M90, IEC 60601-1-4, IEC 60601-1 and is Retlif Certified to the EMC Medical Standard IEC 60601-1-2.

The radionuclide dose calibrators are Class II devices.
Classification #: 90 KPT, 21 CFR #892.1360

The Atomlab dose calibrators comply with Performance Standard IEC 1303 and IEC 61145.

Predicate Devices: Atomlab 100 (K884312/A), Atomlab 200 (K884312/A), Capintec 25 (K071396).

The basic detection, measurement process, design concepts, functionality, calculations and algorithms remain the same as the predicate devices. Testing has been done by physicists at Northwestern Memorial Hospital and Stony Brook University Hospital of device accuracy, linearity, constancy, and geometry to determine that device performance is substantially equivalent to the predicate devices.

The intended use: The Atomlab dose calibrators are used in Nuclear Medicine departments, clinics and nuclear pharmacies for calibrating radioactive doses for administration to patients. The instrument is used to verify the radioactivity of a radionuclide before administration to the patient. The Atomlab dose calibrator is comprised of a display unit and one or more connected argon gas filled pressurized ionization chamber detector unit. The calibration for the dose calibrator is contained in the chamber. Each chamber has a calibration certificate with it when it is shipped. Any of the Atomlab 400 and 500 displays can be connected to the chamber and will work correctly with the chamber since the calibration is stored in the chamber. The dose calibrators were independently tested and verified that they function correctly.

Dose calibrators have been used in Nuclear Medicine departments and nuclear pharmacies for many years. When a dose calibrator is received, upon installation there is a series of tests that are performed by the user or a consulting physicist for acceptance testing of the dose calibrator.

The Atomlab 400 and Atomlab 500 will be manufactured and calibrated to the product's specifications.

CERTIFICATION:
I hereby certify that this summary of safety and effectiveness applies for the above indicated Atomlab dose calibrators.

Date: Jan. 6, 2009

Name: _____

Clyde Schlein
Director of Regulatory Affairs & Compliance
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DEPARTMENT OF HEALTH & HUMAN SERVICES

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Biodex Medical Systems, Inc.
% Mr. Jay Y. Kogoma
Responsible Third Party Official
Intertek Testing Services
2307 E. Aurora Rd., Unit B7
TWINSBURG OH 44087

FEB 19 2009

Re: K090296
Trade/Device Name: Atomlab 400 and Atomlab 500
Regulation Number: 21 CFR 892.1360
Regulation Name: Radionuclide dose calibrator
Regulatory Class: II
Product Code: KPT
Dated: February 5, 2009
Received: February 6, 2009

Dear Mr. Kogoma:

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 os 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 Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (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 Manufactures, 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.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090296

Device Name: Atomlab 400
Atomlab 500

Indications For Use:

The Atomlab dose calibrators are used in Nuclear Medicine Departments, clinics and nuclear pharmacies for calibrating radioactive doses for administration to patients.

The instrument is used to verify the radioactivity of a radionuclide before administration to the patient.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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
510(k) Number K090296