K974651

15. 510(k) Summary - Abbott AxSYM® System

FEB 12 1998

Summary of Safety and Effectiveness Information Supporting a Substantially Equivalent Determination

The following information presented in the 510(k) Notification for the Abbott AxSYM System supports a determination of substantial equivalence:

The Abbott AxSYM System is a fully automated immunoassay analyzer designed to perform Microparticle Enzyme Immunoassay (MEIA), Fluorescence Polarization Immunoassay (FPIA), Radiative Energy Attenuation (REA), and Ion Capture (IC) Immunoassay Technologies. The unique features of the AxSYM System allow it to perform random access, continuous access, and STAT processing of both large and small molecular weight analytes.

The Abbott AxSYM System is substantially equivalent to the Abbott AxSYM II System in that:

a. Both systems may be used to perform assays for large and small molecular weight analytes.

b. Both systems may be used to perform assays for therapeutic drugs.

c. Both systems use Microparticle Enzyme Immunoassay (MEIA), Fluorescence Polarization Immunoassay (FPIA), and Ion Capture (IC) Immunoassay Technologies for the quantitation of antigen-antibody and protein binding reactions. Both systems use Radiative Energy Attenuation (REA) Assay Technology to quantitatively measure specific analyte concentrations.

d. Both systems determine unknown concentrations of analytes from a standard curve generated with known analyte concentrations or qualitatively determine analyte concentrations by comparison to an established cutoff value.

e. Both systems utilize a microprocessor for system control, data acquisition and data reduction.

f. Both systems automatically process samples in a random access mode (tests are processed in a random manner, dependent on the sample presented, and independent of the assay requested) as well as in a continuous access mode (samples may be presented for processing at any time the system is in operation). Both systems also have STAT capability.

When AxSYM MEIA, FPIA, Ion Capture and REA technologies were compared to AxSYM II using patient samples, correlation coefficients ranged from 0.98 to 0.99.

These data support the determination of substantial equivalence of the Abbott AxSYM System to the Abbott AxSYM II System.

Prepared and Submitted January 12, 1998 by:

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
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FEB 12 1998

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Re: K974651
Abbott AxSYM System
Regulatory Class: I
Product Code: JJE
Dated: December 5, 1997
Received: December 8, 1997

Dear Ms. O'Brien:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K974651

Device Name: Abbott AxSYM® System

Indications For Use:

21 CFR § 862.2160 Discrete photometric chemistry analyzer for clinical use

(a) *Identification.* A discrete photometric chemistry analyzer for clinical use is a device intended to duplicate manual analytical procedures by performing automatically various steps such as pipetting, preparing filtrates, heating, and measuring color intensity. This device is intended for use in conjunction with certain materials to measure a variety of analytes. Different models of the device incorporate various instrumentation such as micro analysis apparatus, double beam, single, or dual channel photometers, and bichromatic 2-wavelength photometers. Some models of the device may include reagent-containing components that may also serve as reaction units.

(b) *Classification.* Class I.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K974651

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)