FEB 1 3 2004

Summary of Safety and Effectiveness

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: K033191

Submitter's Name and Address

Bayer Healthcare LLC
511 Benedict Avenue
Tarrytown, NY 10591
Establishment Registration Number: 2432235

Contact Person: Andres Holle
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Contract Manufacturer

Fisher Diagnostics
8365 Valley Pike
Middletown, VA 22645-0307
Establishment Registration: 1181121

Device Name:	Specific Protein Reference Serum
Proprietary/Trade Name	Specific Protein Reference Serum
Common Name:	Calibrator Material
Classification Name:	Calibrator
Classification:	Class II
Regulation Number:	21 CFR 862.1150
Panel:	Chemistry (75)
Product Code:	JIX

Predicate Device:

Specific Protein Reference Serum
Premarket Notification Number: K833402

Device Description:

The Bayer Specific Protein Reference Serum are for one absolute value of calibrator material prepared in human serum with non-serum constituents added.

All the analytes currently in the calibrator material are:
C3
C4
IgA
IgG
IgM
Transferrin
Alpha-1-Acid Glycoprotein
Alpha-1-Antitrypsin
Haptoglobin
Ceruloplasmin

The intention of this submission is to add the assigned values to the labeling claims for use in the US for:
Haptoglobin

Intended Use:

For in vitro diagnostic use in the calibration of the ADVIA 1650 Technicon RA-500, Technicon RA-1000, Technicon RA-XT, Technicon RA-2000, opeRA chemistry systems specific protein methods.

Substantial Equivalence:

The Specific Protein Reference Serum are identical in intended use, storage and handling, stability, source material (human serum), and instructions for use as the previously cleared Specific Protein Reference Serum. The only difference in these calibrators is the addition of the assigned values in the labeling of one new analyte: Haptoglobin.

As with the predicate device, the calibrator materials are a human serum concentrate and dilution is needed with the Specific Protein Sample Diluent provided. These calibrators are for use on the Bayer ADVIA 1650, Technicon RA-1000, Technicon RA-XT, Technicon RA-500, Technicon RA-2000, opeRA chemistry analyzers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 1 3 2004

Mr. Andres Holle
Manager, regulatory Affairs
Bayer Healthcare, LLC
Diagnostics Division
511 Benedict Avenue
Tarrytown, NY 10591

Re: k033791
Trade/Device Name: Specific Protein Reference Serum
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX
Dated: November 17, 2003
Received: December 23, 2003

Dear Mr. Holle:

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K033791

Device Name: Specific Protein Reference Serum

Indications for Use:

For in vitro diagnostic use in the calibration of the ADVIA 1650 Technicon RA-500, Technicon RA-1000, Technicon RA-XT, Technicon RA-2000, opeRA chemistry systems specific protein methods.

(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)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033791