

K974029

1. Following is the revised Summary of Safety and Effectiveness:

Summary of Safety and Effectiveness

FEB 12 1998

As required by 21 CFR 807.92, the following 510(k) Summary is provided:

1. Submitter Information

FEB 12 1998

Contact person: Thomas F. Flynn

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Medfield, MA 02052

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Date Summary Prepared: September 11, 1997

2. Device Information

Proprietary Name: ACS Tobramycin
Common Name: Tobramycin Immunoassay
Classification Name: Class II Tobramycin Test System, 21 CFR 862.3900

3. Predicate Device Information

Name: TDX/FLx Tobramycin Immunoassay
Manufacturer: Abbott Laboratories
510(k) Number: Not Known

4. Device Description

The Chiron Diagnostics ACS:180 Tobramycin assay is a competitive immunoassay using direct, chemiluminescent technology. Tobramycin in the patient sample competes with acradinium ester-labeled tobramycin in the Lite Reagent for a limited amount of monoclonal mouse anti-tobramycin antibody, which is covalently coupled to the paramagnetic particles in the Solid Phase. An inverse relationship exists between the amount of tobramycin present in the patient sample and the amount of relative light units (RLUs) detected by the ACS:180® system.

5. Statement of Intended Use

For the quantitative determination of tobramycin in serum or plasma using the Chiron Diagnostics ACS:180® Automated Chemiluminescence Systems.

6. Summary of Technological Characteristics

The Chiron Diagnostics ACS Tobramycin assay is a competitive chemiluminescent immunoassay.

7. Performance Data

Sensitivity

The ACS Tobramycin immunoassay measures tobramycin concentration up to 13 µg/mL with a minimum detectable concentration of 0.18 µg/mL.

Accuracy

For 293 samples in the range of 0.22 to 9.03 µg/mL, the correlation between the ACS:180 Tobramycin and an alternate fluorescence polarization (FPIA) method is described by the equation:

$$\text{ACS:180 Tobramycin} = 0.903 (\text{alternate method}) + 0.10 \mu\text{g/mL}$$

$$\text{Correlation coefficient } (r) = 0.99$$



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Thomas F. Flynn
Manager, Regulatory Affairs & Compliance
CHIRON DIAGNOSTICS CORPORATION
63 North Street
Medfield, MA 02052

FEB 12 1998

Re: K974029
Trade Name: ACS Tobramycin
Regulatory Class: II
Product Code: LCR 91
Dated: December 23, 1997
Received: December 24, 1997

Dear Mr. Flynn:

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 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.

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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 at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>"

Sincerely yours,



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 (if known): K 97 4029

Device Name: Chiron Diagnostics ACS:180 Tobramycin Assay

Indications for Use:

The Chiron Diagnostics ACS:180 Tobramycin Assay is for the quantitative determination of tobramycin in serum or plasma using the Chiron ACS:180 Automated Chemiluminescence Systems. Monitoring the patient's serum or plasma tobramycin levels is important both to ensure that the drug is present in therapeutic concentrations and to avoid toxicity.

Andrew J. AWM
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number 129740 29

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)