K970546

JUL 14 1997

Company Confidential

Summary of Safety and Effectiveness

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

1. Submitter Information

Contact person:	Thomas F. Flynn
Address:	Chiron Diagnostics Corporation 63 North Street Medfield, MA 02052 Phone: (508) 359-3877 FAX: (508) 359-3885 e-mail: thomas.flynn@chirondiag.com
Date Summary Prepared:	January 31, 1997

2. Device Information

Proprietary Name:	ACS Digitoxin
Common Name:	Digitoxin Immunoassay
Classification Name:	Class II Digitoxin Test System, 21 CFR 862.3300

3. Predicate Device Information

Name:	TDX Digitoxin Immunoassay
Manufacturer:	Abbott Laboratories
510(k) Number:	Not Known

4. Device Description

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

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5. Statement of Intended Use

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

6. Summary of Technological Characteristics

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

7. Performance Data

Sensitivity

The ACS Digitoxin immunoassay measures digitoxin concentration up to 80 ng/mL with a minimum detectable concentration of 1.5 ng/mL.

Accuracy

For 608 samples in the range of 1.5 to 60 ng/mL, the correlation between the ACS:180 Digitoxin and an alternate fluorescence polarization (FPIA) method is described by the equation:

ACS:180 Digitoxin = 0.79 (alternate method) + 4.9 ng/mL

Correlation coefficient (r) = 0.83

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, Massachusetts 02052-1688

JUL 14 1997

Re: K970546
ACS Digitoxin Immunoassay
Regulatory Class: II
Product Code: LFM
Dated: June 26, 1997
Received: June 27, 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 (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 requirement, 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 (if known): _____

Device Name: Chiron Diagnostics ACS:180 Digitoxin Assay

Indications for Use:

The Chiron Diagnostics ACS:180 Digitoxin Assay is for the quantitative determination of digitoxin in serum or plasma using the Chiron ACS:180 Automated Chemiluminescence Systems. Routine monitoring of serum digitoxin concentrations is necessary to maintain therapeutic efficacy and avoid toxicity. Serum digitoxin levels combined with other clinical data provide the clinician with useful information to aid in adjusting patient dosage, achieving optimal therapeutic effect, and avoiding useless subtherapeutic or harmful toxic doses.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K970546

(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)