K97 11418

JUL 17 1997

ACS Centaur

Summary of Safety and Effectiveness

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

1. **Submitters Information**

Contact person: William J. Pignato
Director of Regulatory Affairs

Address: Chiron Diagnostics Corporation
63 North Street
Medfield, MA 02052

Phone: 508 359-3825

Date Summary Prepared: April 14, 1997

2. **Device Information**

Proprietary Name: ACS:Centaur Analyzer
Common Name: Automated Immunoassay Analyzer
Classification Name: Photometric Analyzer for Clinical Use
Classification Number: 21 CFR 862.2160, Class I

3. **Predicate Device Information**

Name: ACS:180® Analyzer
Manufacturer: Chiron Diagnostics Corporation (formally Ciba Corning Diagnostics Corp.)
510(k) Number: D.C. #K902336.

4. **Device Description**

The ACS:Centaur system is a stand-alone, continuous operation, immunochemistry analyzer. The system performs the following functions.

- aspirates and dispenses samples
- performs dilutions
- adds reagents
- incubates reaction vessels
- separates solid and liquid waste
- measures photon emissions
- performs data reduction
- collects and maintains patient demographics and results

5. Statement of Intended Use

The intended use of the ACS:Centaur system is an automated immunoassay analyzer designed to perform in vitro diagnostic immunochemical assays analysis on clinical specimens using the ACS iImmunoassays. The system menu will include endocrine, anemia, reproductive, cardiac, therapeutic drug, and infectious disease assays. All assays are based on chemiluminescent technology.

6. Summary of Technological Characteristics

ACS assays are dedicated for use on the ACS:180® and the ACS:Centaur utilizes acridinium ester as label and paramagnetic particles as the solid phase. Like the ACS:180®, the ACS:Centaur measures the amount of light emitted during the chemiluminescent reaction. There is direct relationship between the amount of light emitted and amount of antigen in the patient sample. The system will measure both competitive binding assays and sandwich assays.

The ACS:Centaur system uses a Master Curve and a two-point, user-initiated calibration to calibrate all the ACS assays. The Master Curve and the two-point calibration system eliminate the need to measure a full standard curve with each assay or to run calibrators each time the assay is run. The system stores the calibration for the interval specified in the assay product inserts.

Other Technological Features include:

- Photomultiplier used in the photon counting mode
- Automated pipetting of sample and reagents
- Electronic Fluid Sensing on sample and reagents
- Clog detection for samples
- Random access and batch test processing
- Varied test incubations
- Human Interface features including barcode reading, LIS, automated data reduction.
- Automated dilution capabilities

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 17 1997

Thomas F. Flynn
Manager, Regulatory Affairs & Compliance
Chiron Diagnostics Corporation
63 North Street
Medfield, Massachusetts 02052-1688

Re: K971418
ACS Centaur Analyzer
Regulatory Class: I
Product Code: JJE
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:Centaur System**

Indications for Use:

The intended use of the ACS:Centaur system is an automated immunoassay analyzer designed to perform in vitro diagnostic immunochemical assays analysis on clinical specimens using the ACS ilmmunoassays. The system menu will include endocrine, anemia, reproductive, cardiac, therapeutic drug, and infectious disease assays. All assays are based on chemiluminescent technology.proteins and is an indirect indicator of thyroid status.4

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number 4/7/97 18

(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)