K991268

AUG 11 1999

510(k) Summary
Sierra Diagnostics, Inc.
GONOSTAT® Gonococcal Detection Kit

I. General Information on Submitter:

Name: Sierra Diagnostics, Inc.
Address: Suite C
21109 Longeway Road
Sonora, CA 95370
Telephone: (209) 539-0886
Fax: (209) 539-0853
Name of Contact Person: Tony K. Baker

Date Summary Prepared: April 13, 1999

II. General Information on Device

Name: GONOSTAT® Gonococcal Detection Kit

Classification Name: DNA Reagents, Neisseria

III. Predicate Device: GONOSTAT® Gonococcal Detection Kit

IV. Description of the Device:

The device is a modification of the predicate device which is also marketed by Sierra Diagnostics, Inc. The device labeling was changed to reflect the results of additional clinical studies that support claims for the use of the device in low prevalence female populations.

V. Intended Use:

Presumptive detection of Neisseria gonorrhoeae based on the detection of gonococcal DNA in female endocervical and male urethral specimens. Because of some cross-reactivity with DNA from N. meningitidis and some other members of the genus Neisseria, the test cannot be used with rectal or throat specimens.

VI. Technological Characteristics of Device Compared to Predicate Device:

The technological characteristics of the two devices are identical

VII. Summary of Clinical Data

An additional clinical study was performed using endocervical specimens at five study sites. The results of this study support the following changes and additions to the product labeling:

a) A new table of female endocervical specimen results obtained from the new study has been added. A summary of the table contents is provided below (N=3318):

Sensitivity:	98.3%
Specificity:	99.3%
Predictive value positive:	94.4%
Predictive value negative:	99.8%

c) Deletion of statements concerning lack of data in low prevalence populations.

d) An analysis of prevalence by sample type and clinical site has been added.

e) A chart of hypothetical predictive values at different prevalence rates has been added.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 11 1999

Sierra Diagnostics
Mr. Donald R. Stone
c/o McKenna & Cuneo, L.L.P.
1900 K Street, N.W.
Washington, D.C. 20006

Re: K991268
Trade Name: GONOSTAT® Gonococcal Detection Kit
Regulatory Class: II
Product Code: LSL
Dated: June 28, 1999
Received: June 29, 1999

Dear Mr. Stone:

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 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). 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 at (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

Indications for Use Statement

510(k) Number: K991268

Device Name: GONOSTAT® Gonococcal Detection Kit

Indications For Use:

The GONOSTAT® Gonococcal Detection Kit is indicated for the presumptive detection of *Neisseria gonorrhoeae* based on the detection of gonococcal DNA in female endocervical and male urethral specimens. Because of some cross-reactivity with DNA from *N. meningitidis* and some other members of the genus *Neisseria*, the test cannot be used with rectal or throat specimens.

Woody Dickens

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K991268

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 C.F.R. § 801.109)