

K982210

JUL 9 1998

Summary: "Special (510): Device Modification"

Syva MicroTrak II Chlamydia EIA K982210

Addendum July 02, 1998

The Syva MicroTrak II Chlamydia EIA has been modified in that the preservative system in the Enzyme/Antibody reagent has been changed to meet USP Challenge test requirements and to be effective against pseudomonads and staphylococci. The modified preservative system meets those design requirements without affecting the performance characteristics, claims, and labeling of the assay as compared to the product with the unmodified preservative system.

Paul Rogers, Sr. Mgr. Regulatory Affairs,



JUL 9 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Paul Rogers
Senior Manager, Regulatory Affairs
Dade Behring, Inc.
P.O. Box 49013
San Jose, CA 95161-9013

Re: K982210
Trade Name: Syva Micro Trak II Chlamydia EIA
Regulatory Class: I
Product Code: LJC
Dated: June 22, 1998
Received: June 23, 1998

Dear Mr. Rogers:

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.

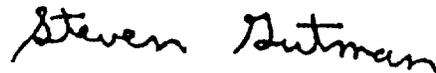
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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):

Device Name: Syva MicroTrak II Chlamydia EIA

Indications For Use: The Syva MicroTrak II Chlamydia EIA is a n enzyme immunoassay intended for use in the qualitative detection of *Chlamydia* in female endocervical, male urethral, male urine and ocular specimens.

The assay may be used to detect the presence of chlamydia where infection is suspected or likely to exist

(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)

Woody Dubois
(Division Sign Off)

Division of Clinical Laboratory Devices

510(k) Number K982210