APR 16 2007

K070174

510(k) Summary – AMPLICOR CT/NG test for Chlamydia trachomatis with Roche Scripts for AMPLICOR CT/NG Test Accessory

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence

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Submitter name, address, contact

Roche Diagnostics
9115 Hague Rd
Indianapolis IN 46250
(317) 521-3723

Contact person: Theresa A. Bush

Date prepared: January 17, 2007

Device Name

Proprietary Name: AMPLICOR CT/NG test for *Chlamydia trachomatis;* Roche Scripts for AMPLICOR CT/NG Test (Roche Scripts Accessory)

Common name: Chlamydia trachomatis test system; software accessory

Classification name: DNA probe, nucleic acid amplification, chlamydia

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Device Description

The AMPLICOR CT/NG test for *Chlamydia trachomatis* is a qualitative in vitro test for the detection of *C. trachomatis DNA* in urine from symptomatic or asymptomatic males, in endocervical swab specimens from symptomatic or asymptomatic females, and in urethral swab specimens from symptomatic males as evidence infection with *C. trachomatis. C. trachomatis DNA* is detected by Polymerase Chain Reaction (PCR) amplification of target DNA and by hybridization capture of amplified target using the AMPLICOR analyzer.

The Roche Scripts for AMPLICOR CT/NG Test accessory consists of a compact disc (CDs) containing scripts to direct the automated Tecan Genesis RSP 150 workstation to process swab samples or control material for analysis.

Continued on next page

Intended use

The AMPLICOR CT/NG test for *Chlamydia trachomatis* is a qualitative in vitro test for the detection of *C. trachomatis DNA* in urine from symptomatic or asymptomatic males, in endocervical swab specimens from symptomatic or asymptomatic females, and in urethral swab specimens from symptomatic males as evidence infection with *C. trachomatis*. *C. trachomatis DNA* is detected by Polymerase Chain Reaction (PCR) amplification of target DNA and by hybridization capture of amplified target using the AMPLICOR analyzer.

Roche Scripts for AMPLICOR CT/NG Test: The Roche Scripts for AMPLICOR CT/NG Test are intended to provide software scripts to direct the automated Tecan Genesis RSP 150 Workstation to process swab samples or control material for analysis using either of the following 510(k)-cleared assay test systems:

- AMPLICOR ® CT/NG test for Chlamydia trachomatis
- AMPLICOR ® CT/NG test for Neisseria gonorrhoeae

Predicate Device

We claim equivalence to the currently marketed AMPLICOR CT/NG test for *Chlamydia trachomatis* cleared under K973707.

Comparison - similarities

The table below shows the similarities between the AMPLICOR CT/NG test for *Chlamydia trachomatis* with optional Roche Scripts accessory and the predicate device:

Feature	Predicate Device: K973707 AMPLICOR CT/NG test for *Chlamydia trachomatis*	Current Device: AMPLICOR CT/NG test for *Chlamydia trachomatis* with optional Roche Scripts accessory
Product features		
Intended use	The AMPLICOR CT/NG test for *Chlamydia trachomatis* is a qualitative in vitro test for the detection of *C. trachomatis DNA* in urine from symptomatic or asymptomatic males, in endocervical swab specimens from symptomatic or asymptomatic females, and in urethral swab specimens from symptomatic males as evidence of infection with *C. trachomatis*. *C. trachomatis DNA* is detected by Polymerase Chain Reaction (PCR) amplification of target DNA and by hybridization capture of amplified target.	Same intended use for AMPLICOR CT/NG test. Roche Scripts for AMPLICOR CT/NG Test: The Roche Scripts for AMPLICOR CT/NG Test are intended to provide software scripts to direct the automated Tecan Genesis RSP 150 Workstation to process swab samples or control material for analysis using either of the following 510(k)-cleared assay test systems: • AMPLICOR ® CT/NG test for Chlamydia trachomatis • AMPLICOR ® CT/NG test for Neisseria gonorrhoeae
Test principle	DNA detection via PCR amplification of target DNA followed by hybridization capture of amplified target using the AMPLICOR Analyzer	Same

Feature	Predicate Device: K973707 AMPLICOR CT/NG test for *Chlamydia trachomatis*	Current Device: AMPLICOR CT/NG test for *Chlamydia trachomatis* with optional Roche Scripts accessory
Controls provided	Positive control: plasmid DNA from C. trachomatis Negative control: plasmid DNA from N. gonorrhoeae Optional internal control: plasmid DNA with CT primer binding regions and a unique probe binding region	Same
Labeled test performance		
Analytical specificity	Negative results from 133 bacteria, 6 fungal, 1 protozoan and 11 viral strains.	Same
Analytical sensitivity	1 IFU/test; equivalent to 20 IFU/mL for urine specimens and 80 IFU/mL for Culture Transport Medium (CTM) with swab specimen)	Manual preparation: Same Automated preparation: 20 IFU/mL for CTM with swab specimen
Precision	100% correct results for panels of CTM and urine specimens.	Manual preparation: Same Automated preparation: 99.6% correct results for panels of CTM specimens
Clinical performance	Sensitivity vs. culture: • 94.1 % for females • 92.9 % for males Specificity vs. culture: • 98.4 % for females • 94.7 % for males (with internal control)	Manual preparation: Same Automated preparation: 98.5% concordance with manual method

Comparison-differences

The table below shows the differences between the AMPLICOR CT/NG test for *Chlamydia trachomatis* with optional Roche Scripts accessory and the predicate device:

Feature	Predicate Device: K973707 AMPLICOR CT/NG test for *Chlamydia trachomatis*	Current Device: AMPLICOR CT/NG test for *Chlamydia trachomatis* with optional Roche Scripts accessory
Specimen and control preparation options	Manual	• Manual or • Automated preparation using the Roche Scripts to direct the Tecan Genesis RSP 150 workstation
Specimen types	Male urine specimens; endocervical and urethral swabs	Manual: same Automated preparation: endocervical and urethral swabs only (no urine samples)

Performance evaluation

The Roche Scripts were developed and evaluated according to FDA Guidance documents.

The AMPLICOR CT/NG test for *Chlamydia trachomatis* with Roche Scripts accessory was evaluated for analytical performance characteristics including analytical sensitivity, cross-contamination, precision, and non-clinical specificity. Results were equivalent to those obtained with manual specimen preparation.

A clinical evaluation was performed where the results obtained using the AMPLICOR CT/NG test for *Chlamydia trachomatis* with automated specimen preparation using the Roche Scripts to direct the Tecan Genesis RSP 150 workstation were compared to results obtained with the manual specimen preparation method. Results were equivalent to those obtained with manual specimen preparation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Indianapolis, IN 452650-0416

APR 16 2007

Re: k070174
Trade/Device Name: AMPLICOR CT/NG test for *Chlamydia trachomatic*
Roche Scripts for AMPLICOR CT/NG Test Accessory
Regulation Number: 21 CFR 866.3120
Regulation Name: Chlamydia Serological Reagents
Regulatory Class: Class II
Product Code: MKZ
Dated: January 17, 2007
Received: January 18, 2007

Dear Dr. Bush:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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.

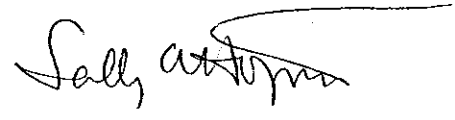
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240)276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070174

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Sample and control preparation can either be accomplished manually or automated using the optional Roche Scripts for AMPLICOR CT/NG Test accessory to direct the Tecan Genesis RSP 150 workstation. Urine specimens are not indicated for use with the automated sample preparation option.

Prescription Use **XXXX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

Indications for Use

510(k) Number (if known): K070174

Device Name: Roche Scripts for AMPLICOR CT/NG Test Accessory

Indications For Use:

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Page 1 of 1

Office of In Vitro Diagnostic Device
Evaluation and Safety

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Office of In Vitro Diagnostic Device Evaluation and Safety

Indications for Use

510(k) Number (if known): k070174

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Page 1 of 1

510(k) k070174