K032334

JAN 1 2 2004

Roche ONLINE Lidocaine Assay

510(k) Summary

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.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 845-2000

Contact Person: Mike Flis

Date Prepared: July 28, 2003

2) Device name

Roche ONLINE TDM Lidocaine

3) Predicate device

We claim substantial equivalence to the Roche COBAS INTEGRA Lidocaine [K954992].

4) Device Description

The assay is a homogeneous immunoassay based on the principle of measuring changes in scattered light or absorbance which result when activated microparticles aggregate. The microparticles are coated with lidocaine and rapidly aggregate in the presence of a lidocaine antibody solution. When a sample containing lidocaine is introduced, the aggregation reaction is partially inhibited, slowing the rate of the aggregation process. Antibody bound to sample drug is no longer available to promote microparticle aggregation, and subsequent particle lattice formulation is inhibited. Thus, a classic inhibition curve with respect to lidocaine concentration is obtained, with the maximum rate of aggregation at the lowest lidocaine concentration. By monitoring the change in scattered light or absorbance, a concentration-dependent curve is obtained.

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5) Intended use

For the quantitative determination of lidocaine in human serum or plasma on automated clinical chemistry analyzers.

6) Comparison to predicate device

The Roche ONLINE TDM Lidocaine was evaluated for several performance characteristics, including precision, lower detection limit, method comparison, specificity, and interfering substances. All of the evaluation studies gave acceptable results compared to the predicate device. These experiments provide evidence that the Roche ONLINE TDM Lidocaine is substantially equivalent to the currently marketed Roche COBAS INTEGRA Lidocaine Assay. The following table presents the precision and method comparison results.

Roche ONLINE TDM Lidocaine				**Roche COBAS INTEGRA Lidocaine, (Predicate labeling)**		
Versus Roche COBAS INTEGRA Lidocaine Assay (predicate device) N = 99 Y = 1.019X-0.044 R = 0.995 Range = 0.40 to 9.56 µg/mL				Versus FPIA method N = 69 Y= 0.947X + 0.011 R= 0.991		
NCCLS Precision:	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Mean (µg/mL)	1.34	4.47	7.03	1.45	3.54	8.09
CV% (within run)	2.7	1.5	1.9	1.92	1.90	2.99
CV% (total)	6.0	3.4	3.6	2.30	2.07	3.75

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 1 2 2004

Mr. Mike Flis
Regulatory Affairs Principal
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

Re: k032334
Trade/Device Name: Roche ONLINE TDM Lidocaine Assay
Regulation Number: 21 CFR 862.3555
Regulation Name: Lidocaine test system
Regulatory Class: Class II
Product Code: KLR
Dated: October 31, 2003
Received: November 4, 2003

Dear Mr. Flis:

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 (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Roche Diagnostics Corporation

510(k) Number (if known): K032334
Device Name: Roche ONLINE TDM Lidocaine Assay
Indications for Use:

The Roche ONLINE TDM Lidocaine assay is for the quantitative determination of lidocaine in human serum or plasma on automated clinical chemistry analyzers. Lidocaine is an antiarrhythmic agent administered intravenously by either injection or continuous infusion. It is indicated in the acute management of ventricular arrhythmias such as those occurring in relation to acute myocardial infarction, or during cardiac manipulation, such as cardiac surgery. The proposed labeling indicates the Roche/Hitachi 911, 912, 917, and Modular P analyzers can be used with the Roche ONLINE Lidocaine reagent kits.

(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)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K032334