K022851

SEP 2 7 2002

XI. Summary of Safety and Effectiveness

The following information as presented in the Premarket Notification [510(k)] for the pH and Amines External Control Set constitutes data supporting a substantially equivalent determination.

Product:

pH and Amines External Control Set

Manufacturer:

Quidel Corporation
10165 McKellar Court
San Diego, California 92121
U.S.A.

Device Classification:

The device, pH and Amines External Control Set, is similar to other FDA-cleared devices which are used in test systems to demonstrate (verify) test performance. The pH and Amines External Control Set falls within the classification of 21 CFR 862.1660.

The Food and Drug Administration has proposed that Quality Control Material (assayed or unassayed) be classified as Class I.

Intended Use:

The pH and Amines External Control Set is intended for use as external controls in accordance with the package insert instructions for the QuickVue® Advance pH and Amines test or the FemExam® pH and Amines TestCard™. When following these instructions, the Controls are to be used in the same manner as a patient swab specimen. For use by healthcare professionals.

Principle of the Controls:

The Positive Control contains a buffered solution (pH $\geq$ 4.7 and volatile amines > 0.5mM); the Negative Control contains a buffered solution (pH < 4.7 and volatile amines < 0.5 mM). The pH and Amines External Control Set will produce examples of the color response to be expected for negative and positive specimens when tested with the QuickVue Advance pH and Amines test or the FemExam pH and Amines TestCard. These controls are intended for use as external controls to aid in the interpretation of positive and negative test results and verify test and operator performance.

Safety and Effectiveness:

Numerous studies were undertaken to document the performance characteristics and the substantial equivalence of the pH and Amines External Control Set to other commercially available products. These studies include the following:

1. The pH and Amines External Control Set was shown to be similar to other commercially available controls in terms of features and intended use.

2. Inter- and intra-assay precision analysis and lot-to-lot consistency demonstrated that the Controls could be manufactured reproducibility for reliable performance in the QuickVue Advance pH and Amines test or the FemExam pH and Amines TestCard.

Conclusion:

These studies demonstrated the substantial equivalence of the pH and Amines External Control Set to existing products already marketed. They further demonstrated the suitability of the product for laboratory and professional use. Such studies are a critical element in establishing the fundamental safety and effectiveness of the product and its appropriateness for commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 2 7 2002

Ms. Robin Weiner
Vice President
Clinical and Regulatory Affairs
Quidel Corporation
10165 McKellar Court
San Diego, CA 92121

Re: k022851
Trade/Device Name: pH and Amines External Control Set
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: August 26, 2002
Received: August 27, 2002

Dear Ms. Weiner:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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" (21CFR 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,

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

XIII. Indications for Use (Separate Page)

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510(k) Number (if known): K022851

Device Name: **pH and Amines External Control Set**

Indications for Use:

The pH and Amines External Control Set is intended for use with the QuickVue® Advance pH and Amines test and the FemExam® pH and Amines TestCard™. These controls are intended for use as external controls to aid in the interpretation of positive and negative test results and verify test and operator performance. The pH and Amines External Control Set is intended for use by healthcare professionals.

(Division Sign-Off)
Division of Clinical Laborato
510(k) Number K022851

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Prescription Use_____ OR Over-The Counter Use_____
(Per 21 CFR 801.109)