K980646

MAY 6 1998

Section 3-- 510(k) Summary
IL Synthesis™- -- Addition of Bilirubin as a Measured Parameter
(Summary of Safety and Effectiveness)

Submitted by:

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Contact Person:

Carol Marble -- Phone: (781) 861-4467

Summary Prepared:

February 18, 1998

Name of the device:

IL Synthesis™ Addition of Bilirubin as Measured Parameter for Use with Neonate Whole Blood Samples

Classification name(s):

862.1113 Bilirubin (total and unbound) in the neonate test system Class I

Identification of predicate devices:

K832236 Sigma's Bilirubin, Total and Direct

Description of the device/intended use(s):

The IL Synthesis™ is a family of fully automatic, microprocessor controlled, blood gas, electrolytes, glucose, hematocrit and co-oximeter analyzers that was cleared for market by K963800. A new measured co-oximeter parameter is being added on the IL Synthesis™ for the semiquantitative determination of total bilirubin in whole blood from neonates. Elevated bilirubin levels in the blood of newborns is used to aid in indicating the risk of bilirubin encephalopathy (kernicterus).

Statement of how the Technological Characteristics of the Device compare to the Predicate device:

Bilirubin as a measured parameter for use with neonate whole blood samples on the IL Synthesis™ is substantially equivalent in performance, intended use and safety and effectiveness to the predicate device: Sigma's Bilirubin, Total and Direct.

Summary of Performance Data:

In a comparative performance study, 309 whole blood samples ranging in bilirubin level from 0 to 20.0 mg/dL were tested using several IL Synthesis™ instruments and Sigma's Bilirubin, Total and Direct on a spectrophotometer. The results showed a slope of 0.925, an intercept of 1.097 and a correlation coefficient of 0.969 indicating that the results are statistically similar.

A precision study on two sample levels assessed on three different IL Synthesis™ instruments in runs of 5 replicates each gave the following results:

			Instrument 1		Instrument 2		Instrument 3	
Parameter	**Level**	**n**	**mean**	**SD**	**mean**	**SD**	**mean**	**SD**
Bilrubin	1	5	1.1	0.95	0.6	0.78	1.3	0.38
(mg/dL)	2	5	2.3	0.55	1.7	0.49	3.7	0.45

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Carol Marble
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Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, Massachusetts 02173-3190

Re: K980646
IL Synthesis™ - Addition of Bilirubin as a Measured Parameter for Neonate Whole Blood Samples
Regulatory Class: I
Product Code: MQM
Dated: February 18, 1998
Received: February 19, 1998

Dear Ms. Marble:

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 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 (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 (if known): K980646

Device Name: IL Synthesis™ -- Addition of Bilirubin as Measured Parameter for Neonate Whole Blood Samples

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

vision Sign-Off)
vision of Clinical Laboratory Devices
510(k) Number K980646

Prescription Use ✓ **OR** Over-The-Counter Use _____
(Per 21 CFR 801.019)