K994438

FEB 4 2000

510(k) Premarket Notification Summary for SpectRx BiliChek Non-Invasive Bilirubin Analyzer

1. SPONSOR

SpectRx, Inc.
6025A Unity Drive
Norcross GA 30071

Contact Person: Mr. Keith D. Ignotz
Telephone: 770-242-8723

Date Prepared: December 29, 1999

2. DEVICE NAME

Proprietary Name:	BiliChek Non-invasive Bilirubin Analyzer
Common/Usual Name:	Non-invasive bilirubin analyzer
Classification Name:	Bilirubin (total and unbound) in the neonate test system (21 CFR 862.1113)

3. PREDICATE DEVICES

Respironics BiliChek Non-invasive Bilirubin Analyzer (K983071)
Chromatics III (K964590)
Leica Unistat Bilirubinometer (K922770).

4. DEVICE DESCRIPTION

The Bilichek consists of the BiliChek hand-held unit, the BiliCal Individual calibration tips, a charger base, and rechargeable battery packs. The BiliChek hand-held unit contains a light source, a fiberoptic probe, a microspectrometer, and a microprocessor control circuit within an 8.5 x 2x 4 inch assembly.

The hand-held unit is battery powered and is controlled by an internal microprocessor. Operator interface with the microprocessor is achieved through three buttons and a liquid crystal display (LCD). The buttons are used to select different set-up options. The measurement is initiated when the operator presses

the Trigger button on the bottom of the unit. The LCD window on the device displays the calculated bilirubin value, date and time, battery status, and permits the unit set-up parameters to be programmed.

The BiliCal disposable tips protect the fiber-optic probe, ensure a hygienic contact with the patient, provide a means for calibration of the BiliChek, and serve as a positioning aid. The disposable tip includes a removable target with calibration material which is used in the initial calibration of the device prior to use on each patient. Before a measurement is taken, the BiliChek runs a baseline reference calibration scan which measures the removable target on the tip. After calibration, the target is removed from the tip to expose an optically clear window through which measurements are made. Sensors in the BiliChek detect when the tip is correctly installed and the depression of the tip under pressure when it is applied to the patient.

Two rechargeable nickel-cadmium battery packs are supplied with the system. The battery pack is inserted in the bottom of the BiliChek Hand-held Unit. The BiliChek Hand-Held Unit includes status indicators which indicate if the battery is low or dead. When fully charged, each battery pack provides sufficient power to conduct 100 measurements. The Bilichek battery charger includes two charging wells, one for the Bilichek and the other for the spare battery pack. The charger is provided power from a 110 volt power supply.

5. INTENDED USE

The Bilichek Non-Invasive Bilirubin Analyzer is a computer assisted non-invasive transcutaneous bilirubinometer which is intended as an index to predict serum bilirubin levels in neonates less than eight days old, without regard to gender, gestational age, race, or bodyweight. The Bilichek provides a numerical measurement of predicted bilirubin count in mg/dL within a clinically beneficial range that has been correlated with total serum bilirubin concentration measured by High Pressure Liquid Chromatography (HPLC). The device is used in the hospital or institutional environment to assist clinicians in monitoring the status of neonates for the development of hyperbilirubinemia. Neonates whose Bilichek test results are indicative of hyperbilirubinemia are evaluated by their physician(s) for appropriate patient management

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The SpectRx BiliChek Noninvasive Bilirubin Analyzer is identical to the Respironics BiliChek Noninvasive Bilirubin Analyzer which was cleared by FDA under 510(k) K983071. There are no technological differences between the devices since they are identical.

The BiliChek is substantially equivalent to the Chromatics Color Sciences International Colormate III (K964590) and to the Unistat Bilirubinometer (K922770). All of these devices have similar intended uses and technological characteristics. Each device measures the presence of hyperbilirubinemia in neonates, and each device bases its measurements on the absorbance characteristics of bilirubin in the visible spectrum.

7. PERFORMANCE TESTING

Testing of the SpectRx BiliChek included the following:

a. Biocompatibility: Materials used in the BiliChek were tested for biocompatibility and shown to be safe for use on intact skin.

b. Electrical safety testing. The BiliChek System was tested for compliance with IEC 601-1. The results show that the device complies with the requirements of IEC 601-1.

c. Electronic hardware testing: Functional testing of the printed circuit boards for the main board and charger board was performed and demonstrated that these boards meet their respective performance specifications.

d. BiliChek Battery and Temperature Testing: These tests verified that the BiliChek battery pack will operate the BiliChek for at least 100 measurements. In addition, the tests verified that the BiliChek meets specifications for operating over the specified temperature range of +5°C to +40°C.

e. Calibration Material Stability: The calibration material was exposed to elevated temperature for an extended period of time to simulate exposure to extreme environmental conditions and to accelerate aging. The material was found to be stable over the tested temperature range.

f. EMI/EMC Testing: Immunity and emissions testing was performed and demonstrates that the BiliChek System complies with the requirements of IEC 601-1-2 for immunity and EN55011 for emissions.

g. Software testing: The software/firmware used in the BiliChek was tested in accordance with the software test plan and demonstrates that the software program meets the performance specifications.

h. Clinical testing: Clinical testing of the BiliChek was conducted to demonstrate the ability of the BiliChek device to non-invasively measure the bilirubin levels of infants less than eight days old prior to the use of phototherapy or any related therapeutic intervention. Bilirubin values measured by HPLC and with the BiliChek were compared to determine the accuracy of the BiliChek. The test results demonstrate a statistically and clinically significant correlation between the BiliChek and serum bilirubin levels as indicated by HPLC. There were no significant differences in the performance of the BiliChek attributed to race, sex, gestational age at delivery, bodyweight, or presence in the NICU. There were no injuries or deaths that occurred while the device was being used or any adverse effects reported from use of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 4 2000

Mr. James R. Veale
Vice President, Regulatory Services
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K994438
Trade Name: BiliChek Non-Invasive Bilirubin Analyzer
Regulatory Class: I reserved
Product Code: MQM
Dated: December 29, 1999
Received: December 30, 1999

Dear Mr. Veale:

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.

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 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

510(k) Number (if known): K994438

Device Name: BiliChek, Non-Invasive Bilirubin Analyzer

Indications For Use:

The BiliChek Non-Invasive Bilirubin Analyzer is a computer assisted non-invasive transcutaneous bilirubinometer which is intended as an index to predict serum bilirubin levels in neonates less than eight days old, without regard to gender, gestational age, race, or bodyweight. The BiliChek provides a numerical measurement of predicted bilirubin count in mg/dL within a clinically beneficial range that has been correlated with total serum bilirubin concentration measured by High Performance Liquid Chromatography (HPLC). The device is used in the hospital or institutional environment to assist clinicians in monitoring the status of neonates for the development of hyperbilirubinemia. Neonates whose BiliChek test results are indicative of hyperbilirubinemia are evaluated by their physician(s) for appropriate patient management.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Bernardt for S. J. Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K 994438

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)