

SEP 22 1998

K972309

510(k) Summary

JM-102 Jaundice Meter

Common/Classification Name: Jaundice Meter
Air-Shields
330 Jacksonville Road
Hatboro, PA 19040

Contact: Marci Goldfinger, Prepared: June 19, 1997

A. LEGALLY MARKETED PREDICATE DEVICES

The JM-102 Jaundice Meter is substantially equivalent to an earlier model of the same device, the JM-101 (P810007).

B. DEVICE DESCRIPTION

The Air-Shields JM-102 Jaundice Meter is a hand-held non-invasive device for the measurement of the level of jaundice in an infant. The system consists of the hand-held meter with digital display, the charger for recharging the NiCd battery pack in the device, a calibration checker, and a carrying case. The device measures the yellowish tint in jaundiced skin by analyzing the light reflected off the skin. The fiber-optic probe on top of the device is held against the infant's skin and an internal flash lamp sends a pulse of light through the outer part of an optical wave guide to the skin where the light is reflected back through the inner part of the optical wave guide and to the spectral analysis section of the device.

C. INTENDED USE

The JM-102 Jaundice Meter is a diagnostic device intended for use on infants suspected of having jaundice to provide an objective index of icterus. This index can be used by a medical practitioner to identify infants who should be given a serum bilirubin test and to identify those infants who do not need a serum test.

Specific action levels have not been developed which apply to infants of less than 36 weeks of gestational age.

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D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **JM-102** has the same indications statement as the predicate device and it has the same technological characteristics. The descriptive characteristics may not be sufficient to ensure equivalence, but performance data are available and they demonstrate equivalence (see Section F, below). Therefore, the decision algorithm brings us to a decision of substantial equivalence.

E. TECHNOLOGICAL CHARACTERISTICS

See Section B, above.

F. TESTING

The only modification to the device which could affect the performance of the device is the spectral response of the green and blue pathways. Testing with a spectrophotometer has demonstrated that the spectral responses are the same.

In addition, a clinical study showed a high degree of correlation between readings on infants taken with the JM-101 and JM-102.



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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

T. Whit Athey, Ph.D.
Senior Consultant
C.L. McIntosh & Associates, Inc.
12300 Twinbrook Parkway, Suite 625
Rockville, Maryland 20852

Re: K972309
JM-102 Jaundice Meter
Regulatory Class: I
Product Code: MQM
Dated: July 17, 1997
Received: July 17, 1997

Dear Dr. Athey:

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.

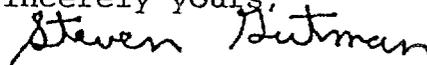
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: JM-102 Jaundice Meter

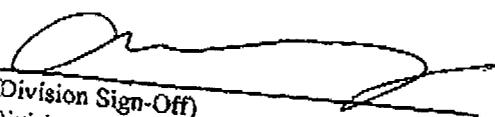
Indications For Use:

The JM-102 Jaundice Meter provides an objective index of icterus in infants and when used in conjunction with other clinical signs and/or laboratory measurements, can assist the physician in making clinical decisions regarding the need for serum bilirubin measurements ~~and/or therapy.~~

9/16/98

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K 972309

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

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