

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE**

A. 510(k) Number:

k133175

B. Purpose for Submission:

Modification of a previously cleared device (k042522)

C. Manufacturer and Instrument Name:

Draeger Jaundice Meter JM-105

D. Type of Test or Tests Performed:

Transcutaneous bilirubin in the neonate (yellowness of skin), quantitative readout

E. System Descriptions:

1. Device Description:

The JM-105 Jaundice Meter is a non-invasive transcutaneous bilirubinometer. It measures yellowness of subcutaneous tissue in newborn infants. The unit provides a visual digital measurement that has been shown to correlate with serum bilirubin in newborn infants.

The JM-105 is a portable, hand held, battery powered device that includes a docking station with a built in reading checker. The JM-105 batteries can be charged using a battery charger or an optional USB cable.

The JM-105 is a modification of the JM-103 Jaundice Meter. The basic functionality including measurement of the JM-105 is equivalent to the JM-103. The display of the JM-105 has been improved (larger screen, touchscreen) and data storage and transmission functionality was added. The measuring probe, hardware, and software used to process the measurements are identical and therefore use the same measuring principle. Both JM-103 and JM-105 determine the yellowness of subcutaneous tissue by using two optical paths to measure the optical density difference at two wavelengths.

The meter contains a “reading checker” to monitor sufficient light output.

2. Principles of Operation:

The transcutaneous bilirubin absorbs blue and green light. The Jaundice Meter

determines the yellowness of the subcutaneous tissue by measuring the difference in the optical densities for light in the blue (450 nm) and green (550 nm) wavelength regions. When the measuring probe is pressed against the sternum or forehead of the infant, the built-in xenon lamp flashes. The light from the xenon lamp passes through the glass fiber and illuminates the skin. The light scatters and is absorbed in the skin and subcutaneous tissue repeatedly, and then finally returns to the sensor side of the glass fiber. The denser the transcutaneous bilirubin, the weaker the reflected blue light. The reflected green light remains unchanged regardless of the density of the bilirubin.

Because the optical density difference shows a linear correlation with the total serum bilirubin concentration, it is converted to the bilirubin concentration and displayed digitally on the device screen.

Measurements must be taken only on the infant's sternum (at hospital sites or physicians' offices) or forehead (at hospital sites only) where a sufficient amount of blood is circulated. A possibility exists that the bilirubin in the subcutaneous tissue may measure low for areas with minimal blood flow or areas in which the subcutaneous tissue is subject to keratinization.

Although correlation with serum bilirubin was observed for both sternum and forehead measurements, the clinical studies performed with the Jaundice Meter show consistently better results with measurements taken at the sternum versus the forehead. There is a possibility that this difference may be more pronounced for infants that have been exposed to sunlight, such as infants seen at doctors' offices. Only sternum measurements were evaluated during the studies conducted at doctors' offices; correlation of forehead measurements with serum bilirubin has not been evaluated, and the device is not intended for forehead measurements at doctors' offices.

3. Modes of Operation:

Manual method- hand held device.

4. Specimen Identification:

Sternum (in hospitals and physician offices) or forehead (in hospitals only) skin of infants > 35 weeks gestation and < 14 days of age.

5. Specimen Sampling and Handling:

Not applicable. This is a non-invasive test, a transcutaneous measurement with an optical probe.

6. Calibration:

Factory calibrated.

7. Quality Control:

The meter contains a “Reading Checker” to monitor sufficient light output. The manufacturer recommends that this be used at least once per day.

8. Software:

FDA has reviewed applicant’s Hazard Analysis and Software Development processes for this line of product types:

Yes ___ X ___ or No _____

F. Regulatory Information:

1. Regulation section:

21 CFR 862.1113, Bilirubin (total and unbound) in the neonate test system

2. Classification:

Class I, reserved

3. Product code:

MQM

4. Panel:

Clinical Chemistry (75)

G. Intended Use:

1. Indication(s) for Use:

The Jaundice Meter (JM-105) is a non-invasive transcutaneous bilirubinometer. It measures yellowness of subcutaneous tissue in newborn infants. The unit provides a visual digital measurement that has been shown to correlate with serum bilirubin in newborn infants.

The device is intended for use in hospitals, clinics or doctor’s offices under a physician’s supervision / direction to assist clinicians in monitoring of newborn infants. The device is not intended as a standalone for diagnosis of hyperbilirubinemia. It is to be used in conjunction with other clinical signs and laboratory measurements.

Newborn infants whose JM-105 Jaundice Meter test results are indicative of hyperbilirubinemia should be evaluated by their physician(s) for appropriate patient

management. Specific neonatal patient Bilirubin levels should be confirmed by other methods, such as serum bilirubin, prior to treatment determinations.

The JM 105 is a prescription medical device

The JM 105 is not intended for home use.

The JM 105 may only be used at the sternum measurement site for Physician’s office applications.

2. Special Conditions for Use Statement(s):

Use only on infants up to 14 days of age.

The Jaundice Meter is indicated for use in neonatal patients born >35 weeks gestation who have not undergone exchange transfusion or phototherapy treatment.

Users must be trained prior to using the device.

The device is indicated for forehead and sternum measurements in hospitals, and only sternum measurements in physician’s offices. Forehead measurements in physician’s offices were not tested and may be more prone to uncertainties.

For prescription use only.

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

Draeger JM-103 Jaundice Meter, k042522

2. Comparison with Predicate Device:

Similarities		
Item	Device JM-105 Jaundice Meter K133175	Predicate JM-103 Jaundice Meter K042522
Intended Use	The Jaundice Meter (JM-105) is a non-invasive transcutaneous bilirubinometer. It measures yellowness of subcutaneous tissue in newborn infants.	Same
Test Principle	Determines the yellowness of subcutaneous tissue by using two optical paths to measure the optical density difference at two	Same

Similarities		
Item	Device JM-105 Jaundice Meter K133175	Predicate JM-103 Jaundice Meter K042522
	wavelengths	
Measuring Range	0.0 – 20.0 mg/dL or 0 -340 µmol/L	Same
Light Source	Pulse Xenon Arc lamp	Same
Sensors	Silicon photodiodes	Same
Averaging function	Single and average of up to 5 measurements	same

Differences		
Item	Device JM-105 Jaundice Meter K133175	Predicate JM-103 Jaundice Meter K042522
Dimensions	56mm(W)×168mm(H)×45mm(D)	48mm(W)x154mm(H)x32mm (D)
Weight	203g (including battery)	150g (including battery)
Data Storage and Transmission	Yes	No
Touchscreen	Yes	No

I. Special Control/Guidance Document Referenced (if applicable):

Not applicable.

J. Performance Characteristics:

The measurement instrumentation is identical between the JM-103 (predicate device) and the JM-105 (candidate device) meters. Only the outer box and user interface has changed. Therefore, the sponsor referenced certain performance data collected on the JM-103 Jaundice Meter and reviewed in k021622 and k042522.

1. Analytical Performance:

a. Accuracy:

Accuracy of the sensor was established in k042522

b. Precision/Reproducibility:

150 units of JM-105 were each used to measure three Master Checkers (0 Checker, 20 Checker and 30 Checker) 10 times. The Master Checkers were used at the manufacturing site to evaluate the precision of the JM-105. The data were reviewed and adequately demonstrated that the device performs with acceptable precision.

c. Linearity:

The device measures up to 20.0 mg/dL of bilirubin.

d. Carryover:

Not applicable

e. Interfering Substances:

Potential interferents were evaluated for this sensor in k042522

2. Other Supportive Instrument Performance Data Not Covered Above:

Usability testing studies were performed on the JM-105 meter to assess whether intended users were able to use the modified device (JM-105 meter) following instructions provided in the labeling. The results of the usability testing showed that the intended users can properly perform the operation of the device.

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.