DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 1, 2015

Children's Mercy Hospital
c/o Mr. Jan S. Peterson
The EMMES Corporation
401 N Washington Street, Suite 700
Rockville, MD 20850

Re: K142469
Trade/Device Name: Mercy TAPE Device (2D and 3D Models)
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual Surgical Instrument for General Use
Regulatory Class: I
Product Code: PIR
Dated: March 31, 2015
Received: April 1, 2015

Dear Mr. Peterson:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142469

Device Name
Mercy TAPE device (2D and 3D models)

Indications for Use *(Describe)*

The Mercy TAPE device (2D and 3D models) is intended to estimate the body weight of pediatric patients between the ages of 2 months and 16 years, using linear measurements from specific anatomical landmarks made with the Mercy TAPE device for humeral length (HL, for the 2D model) or half-humeral length (HHL, for the 3D model) and the mid-upper arm circumference (MUAC).

The Mercy TAPE device may be less reliable for use in children with known or apparent limb deformities, or abnormal body proportions caused by conditions such as edema or severe malnutrition.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K142469

6. 510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.87(h).

A. Submitter's Information

Name: Susan Abdel-Rahman, PharmD

Address: Professor of Pediatrics
Division of Clinical Pharmacology and Medical Toxicology
Children's Mercy Hospital
2401 Gilham Road, RB 3730.06
Kansas City, MO 64108-4619

Phone: 816-234-3059
Fax: 816-855-1958
E-mail: srahman@cmh.edu

Correspondent: Jan S. Peterson, MS, CCRA, RAC
The Emmes Corporation
401 N. Washington Street, Suite 700
Rockville, MD 20850-1785
301-251-1161
jpeterson@emmes.com

Date of Summary: April 30, 2015

B. Device Information

Device Name: Mercy TAPE Device (2D and 3D Models)
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual surgical instrument for general use, Tape Measure
Regulatory Class: I
Product Code: PIR
Panel: General Hospital

C. Predicate Device Information

Manufacturer: Pfizer, Inc.
Product Name: Tape Measure
510(k) Number: K790089
Product code: FTY
Regulation Number: 878.4800

D. Reference Devices

a) Scale, Stand-on, Patient

Manufacturer:	SR Instruments Inc.
Product Name:	Daily-weight
510(k) Number:	K770848
Product code:	FRI
Regulation Number:	880.2700

b) Scale, Patient

Manufacturer:	U.S. Medical Corp
Product Name:	U.S. Medical PS-2000 Pediatric Scale
510(k) Number:	K910582
Product code:	FRW
Regulation Number:	880.2720

E. Device Description

The Mercy TAPE Device (2D and 3D Models) consists of semi-durable or disposable flexible strips of coated paper, fabric or plastic tape printed with numbered bins proportional to fractional body weight of pediatric patients. The markings correspond to the validated Mercy Method (calculation algorithm) for determining pediatric body weight using humeral length and mid-upper arm circumference.

The Mercy TAPE Device 2D Model consists of a single strip of tape that is used in two (2) stages to measure humeral length and mid-upper arm circumference. For the Mercy TAPE Device 3D Model, two (2) perpendicular strips of tape are designed to be joined into a sliding "T" shape so that humeral length and mid-upper arm circumference can be measured.

F. Intended Use

The Mercy TAPE Device (2D and 3D Models) is intended to estimate the body weight of pediatric patients between the ages of 2 months and 16 years, using linear measurements from specific anatomical landmarks made with the Mercy TAPE Device for humeral length (HL, for the 2D Model) or half-humeral length (HHL, for the 3D Model) and the mid-upper arm circumference (MUAC).

The Mercy TAPE Device may be less reliable for use in children with known or apparent limb deformities, or abnormal body proportions caused by conditions such as edema or severe malnutrition.

Rx only.

G. Summary of comparison with predicate device and reference devices

Attribute	***Mercy TAPE Device (2D and 3D Models)***	**Predicate device: Tape Measure (K790089) Product Code FTY**	**Reference device: Stand-on Patient Scale (K770848) Product Code FRI**	**Reference device: Patient Scale (K910582) Product Code FRW**
Intended Use	*The Mercy TAPE Device (2D and 3D Models) are intended to be used for estimating the weight of a pediatric patient by measuring the length of specific body parts*	A tape measure is a device intended to be used in various general surgical procedures for measuring length of parts of the body	A stand-on patient scale is a device intended for medical purposes that is used to weigh a patient who is able to stand on the scale platform	A patient scale is a device intended for medical purposes that is used to measure the weight of a patient who cannot stand on a scale.
Use for general use	*Yes*	Yes	Yes (when patient can stand)	Yes
Anthropometric measurement	*Yes*	Yes	Yes	Yes
Length measurement of body part	*Yes, converted to weight*	Yes	No	No
Weight Determination	*Yes, based upon measured length of body parts*	No	Yes	Yes
Weight determination method	*Indirect*	No	Direct	Direct
Output Display	*View markings on device and add indicated values*	View markings on device	View display indicator on device	View display indicator on device
Requires Electrical Power	*No*	No	Optional	Optional
Hand-manipulated device	*Yes*	Yes	Optional	Optional
Reusable	*Labeled for Single Patient Use*	Yes	Yes	Yes

H. Performance Evaluation – Clinical Testing

Clinical studies were conducted to evaluate the predictive performance of the Mercy TAPE Device (2D and 3D Models) and their equivalence to the underlying Mercy Tape method algorithm. Non-clinical studies were not performed. In the clinical studies, the device shows acceptably small variability from true weight with minimal bias. The Mercy Tape method algorithm was developed using demographic and anthropometric data on 17,328 individual children 2 months to 16 years of age from the National Health and Nutrition Examination Survey (NHANES) database. In addition, 1,938 datasets were used for method validation.

A separate human factors/usability study was also conducted utilizing the Mercy TAPE Device (2D and 3D Models) to examine the speed, accuracy and precision with which "front-line" health care providers could apply the Mercy TAPE Device (2D and 3D Models). The study included emergency department (ED) nurses and first responders who conducted 1,412 assessments comparing the Mercy TAPE Device (2D and 3D Models) to all five of the most common weight estimation strategies, including visual estimation, Advanced Pediatric Life Support (APLS) calculation, Broselow Tape, Devised Weight Estimation Method, and the Luscombe and Owens formula. Our human factors/usability analyses reveal no significant differences in subjective determinations for ease of use between the Mercy TAPE Device (2D and 3D Models) and existing weight estimation strategies. In addition, the critical task errors observed with the Mercy TAPE Device (2D and 3D Models) occur with a frequency similar to or lower than the error rates observed with standard medical equipment (e.g., scales, stadiometers, and tape measures). Importantly, even when factoring in errors and close-calls, the estimated weights generated by the Mercy TAPE Device (2D and 3D Models) are more accurate than the weights returned with existing weight estimation strategies.

I. Comparison to the Predicate Device and Conclusion

The Mercy TAPE Device (2D and 3D Models) shares certain common features with the predicate comparator device, namely the simple tape measure, in that it assesses simple anthropometric measurements. The Mercy TAPE Device (2D and 3D Models), however, provides an estimation of body weight based on an algorithm that is unique to the device. The Mercy TAPE Device (2D and 3D Models) uses linear anthropometric body measurements to derive estimated body weight, and this has been validated against scales that use mechanical strain or balance methods to obtain an estimate of body weight. The clinical testing indicates that the Mercy TAPE Device (2D and 3D Models) is substantially equivalent to the predicate comparator device and was validated against a mechanical scale to demonstrate equivalent performance.