May 18, 2022

GRI-Alleset, Inc
% Julie Stephens
President
Regulatory Resources Group, Inc.
111 Laurel Ridge Dr
Alpharetta, Georgia 30004

Re: K220917
Trade/Device Name: gentleheel
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual Surgical Instrument For General Use
Regulatory Class: Class II
Product Code: FMK
Dated: March 30, 2022
Received: March 30, 2022

Dear Julie Stephens:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220917

Device Name
gentleheel®

Indications for Use *(Describe)*
The intended use of this device is for newborn babies and toddlers of any ethnicity where a blood sample is desired, and a self-retracting safety feature is desired to protect the clinician performing the blood sampling.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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."

510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements under 21 CFR 807.92.

Submitted By:
GRI-Alleset, Inc.
4142 Industry Way
Flowery Branch, GA 30542 USA
Phone: (678) 523-8977

Contact Person: Julie Stephens, President/Consultant
Regulatory Resources Group, Inc. - Phone: (678) 513-0693

Date Submitted: May 18, 2022

Device Name and Classification:

Trade/Proprietary Name:	gentleheel®
Common Name:	Infant Heel Stick Lancet with Sharps Prevention Feature
Classification Name:	Blood Lancets - Single use only blood lancet with an integral sharps injury prevention feature
Regulation Number:	21 CFR 878.4850
Class:	II
Product Code:	FMK

Legally Marketed Predicate Device:

Primary Predicate: GRI gentleheel®, 510(k) # K172712
Additional Predicate: ITC Tenderfoot®, 510(k) # K883968 & K911997 [Current: Accriva Diagnostics, Inc.]

Device Description:

The gentleheel® is designed to be an easy to use, safe, one handed heel incision device for acquiring blood samples from the heels of newborns. The welded plastic housing is designed to prevent accidental exposure to the blade, to be ergonomic for improved handling, and compatible with an infant's foot. The user is instructed to remove the trigger lock. When the gentleheel is placed against the infant's heel and the user presses the trigger mechanism it automatically makes the incision by starting the blade in a continuous motion from inside the housing, into the infant's heel, and then back within the housing. The trigger mechanism is no longer functional and the blade remains inside the housing through disposal. The entire device is discarded in a sharps container after use. The gentleheel devices are provided sterile and are single patient use only. They are sterilized by Ethylene Oxide (EO) sterilization method.

The gentleheel comes in models for Newborn (NGH), Preemie (PGH), Micro-Preemie (MPGH), and Toddler (TGH). The models are differentiated by the styles and colors of the housing (see following definitions).

510(k) Summary

Toddler (Color - Blue)	Children between the ages 6 months and 2 years or greater than 19.8 lbs. (9 kilograms)
Newborn (Color - Green)	A full term baby is born at 37 weeks or after
Preemie (Color - Pink)	The technical term for preemie is defined as a baby that is under 5.5 pounds (2500 grams), and usually is born prior to 37 weeks of gestation
Micro-Preemie (Color - Yellow)	To an NICU medical professional, a micro-preemie is defined as a baby that is under 1.75 lbs. (between 700-800 grams) and is generally born before 26 weeks gestation, but most people prefer to loosen this term up to include any baby under 3 lbs. (1500 grams) or under 29 weeks gestation

Indications / Intended Use:

The intended use of this device is for newborn babies and toddlers of any ethnicity where a blood sample is desired, and a self-retracting safety feature is desired to protect the clinician performing the blood sampling.

The Indications / Intended Use statements for the gentleheel [Proposed Device] is substantial equivalent to the gentleheel device previously cleared in 510(k) # K172712 [Primary Predicate Device] and to the Tenderfoot [Additional Predicate Device]. The gentleheel devices and predicates, are intended for piercing the skin on the heel of newborn babies and toddlers and the Indications for Use / Intended Use statements are substantially equivalent.

Comparison of Indications of Use to the Predicate Devices

Proposed Device 510(k) #: K220917	Primary Predicate Device 510(k) #: K172712	Additional Predicate Device 510(k) #: K883968 & K911997
gentleheel®	gentleheel®	Tenderfoot®
The intended use of this device is for newborn babies and toddlers of any ethnicity where a blood sample is desired, and a self-retracting safety feature is desired to protect the clinician performing the blood sampling.	The gentleheel® devices are heel incision devices for blood sampling in newborns, premature and low birth weight infants, and toddlers. The gentleheel has a sharps prevention feature to protect the user from a sharps injury.	Tenderfoot® is a fully automated heel incision device for blood sampling from the heels of newborns, premature, low birth weight infants, and toddlers.

Technological Characteristics:

The gentleheel® devices [Proposed Device] did not change technological characteristics or material specifications from the previously cleared 510(k) # K172712 [Primary Predicate Device]. The gentleheel® devices are substantially equivalent to the Tenderfoot devices [Additional Predicate Device] as they have the same basic technology characteristics for newborn babies and toddlers heel stick lancets with a sharps injury prevention feature. The materials are comparable in that the blades all use medical grade stainless steel and the housings are made of medical grade plastics.

510(k) Summary

Comparison of Technological Characteristics to the Predicate Devices

Proposed Device 510(k) #: K220917	Primary Predicate Device 510(k) #: K172712	Additional Predicate Device 510(k) #: K883968 & K911997
gentleheel®	gentleheel®	Tenderfoot®
Materials		
Stainless steels; plastics	Same - No changes	Surgical steels; plastics
Housing Colors		
Newborn - Green Preemie - Pink Micro-Preemie - Yellow Toddler - Blue	Same - No changes	Newborn - Pink/Blue Preemie - White Micro-preemie - Blue Toddler - Pink
Overall Dimensions		
Length: 1.25 in (3.18 cm) Height: 1.56 in (3.96 cm) - with Lock Height: 1.20 in (3.05 cm) Width: 0.48 in (1.22 cm)	Same - No changes	Length: 1.24 in (3.15 cm) Height: 1.56 in (3.96 cm) - with Lock Height: 1.20 in (3.05 cm) Depth: 0.45 in (1.14 cm)
Labeled Cut Profiles: L-Length and D-Depth (mm)		
Newborn: L-2.50; D-1.00 Preemie: L-1.75; D-0.85 Newborn: L-1.40; D-0.65 Preemie: L-3.00; D-2.00	Same - No changes	Newborn: L-2.50; D-1.00 Preemie: L-1.75; D-0.85 Newborn: L-1.40; D-0.65 Preemie: L-3.00; D-2.00
Safety Features		
Single use only with an integral sharps injury prevention feature. The blade is not exposed except during use, which allows the device to be used once and then renders it inoperable and incapable of further use as the blade automatically retracts at the end of incision motion.	Same - No changes	Single use only with an integral sharps injury prevention feature. The blade is not exposed except during use, which allows the device to be used once and then renders it inoperable and incapable of further use as the blade automatically retracts at the end of incision motion.

Summary of Testing:

The biocompatibility risk assessment was completed as directed by FDA guidance under ISO 10993-1 biocompatibility requirements. Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, Material-Mediated Pyrogenicity, and Hemolysis testing was completed to demonstrate that the known biocompatible materials maintained compliance through manufacturing and sterilization. Performance and safety testing completed for the gentleheel® included tests for cutting profile, trigger force and reverse safety, drop testing, and simulated use testing.

Substantial Equivalence Conclusions:

The gentleheel® has the same principles of operation, intended use, and technological characteristics including the materials used, sizes and dimensions, cutting profiles, and sharps injury prevention features (irreversibly disable the device after one use) as the predicate devices. The sharps prevention feature was fully tested to the FDA's guidance document as demonstrated in the performance testing.