November 5, 2024

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

Re: K242664
Trade/Device Name: gentleheel® Adult Incision Device
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: FMK
Dated: September 4, 2024
Received: November 1, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

James H. Jang -S

Digitally signed by James H. Jang -S
Date: 2024.11.05 23:06:11 -05'00'

For
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242664

Device Name

gentleheel® Adult Incision Device

Indications for Use *(Describe)*

The gentleheel® Adult Incision Device is a single-use lancing device intended to obtain microliter capillary blood samples. The gentleheel® Adult Incision Device has a sharps prevention feature to protect the user from a needlestick injury.

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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510(k) Summary – K242664

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: November 1, 2024

Device Name and Classification:

Trade/Proprietary Name:	gentleheel® Adult Incision Device
Common Name:	Blood 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:

Predicate: GRI gentleheel®, 510(k) # K220917 and K172712

Device Description:

The gentleheel® Adult Incision Device is designed to be an easy to use, safe, one handed incision device for acquiring blood samples from the patient's finger to obtain sufficient blood volumes for capillary blood draws. The gentleheel Adult Incision Device utilizes a blade resulting in improved blood flow requirements. The welded plastic housing is designed to prevent accidental exposure to the blade, to be ergonomic for improved handling, and compatible with a human fingertip. The user is instructed to remove the trigger lock. When the gentleheel Adult Incision Device is placed against the patient's finger 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 fingertip, 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 Adult Incision Devices are provided sterile and are single patient use only. They are sterilized by Ethylene Oxide (EO) sterilization method.

510(k) Summary – K242664

The gentleheel® Adult Incision Device comes in the Catalog/Reference Numbers described as follows:

Catalog/Reference Numbers	Quantity	Case Color	Incision Profile	
			Length	Depth
AGH10x50	50ea/carton X 10 cartons Total 500ea/case	Blue	3.00mm	2.00mm
AGH4X250	250ea/carton X 4 cartons Total 1000ea/case			

Indications for Use:

The gentleheel® Adult Incision Device is a single-use lancing device intended to obtain microliter capillary blood samples. The gentleheel® Adult Incision Device has a sharps prevention feature to protect the user from a needlestick injury.

Comparison of Indications of Use to the Predicate Device

The Indications for Use statement for the gentleheel® Adult Incision Device [Proposed Device] is an additional Indications for Use from the gentleheel device previously cleared [Predicate Device]. The gentleheel Adult Incision Device [Proposed Device] is indicated for adults as the intended patient population. The gentleheel Adult Incision Devices are intended for lancing the skin on the fingertip area of adults.

Proposed Device 510(k) #: Pending	Predicate Device 510(k) #: K220917
gentleheel® Adult Incision Device	gentleheel®
The gentleheel® Adult Incision Device is a single-use lancing device intended to obtain microliter capillary blood samples. The gentleheel® Adult Incision Device has a sharps prevention feature to protect the user from a needlestick injury.	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.

Technological Characteristics:

The gentleheel® devices [Proposed Device] did not change technological characteristics or material specifications from the previously cleared 510(k) # K220917 [Predicate Device].

510(k) Summary – K242664

Comparison of Technological Characteristics to the Predicate Device

Proposed Device 510(k) #: Pending	Predicate Device 510(k) #: K220917
gentleheel® Adult Incision Device	gentleheel®
Materials	
Stainless steels; plastics	Same - No changes
Housing Color	
Blue	Same - No changes
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
Labeled Cut Profiles: Length and Depth (mm)	
Length-3.00; Depth-2.00	Same - No changes
Safety Features - Sharps Injury Prevention	
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

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, and drop testing. Clinical use testing was completed on adults for lancing the fingertip areas of adults to obtain microliter capillary blood samples.

Substantial Equivalence Conclusions:

The gentleheel® Adult Incision Device has the same principles of operation 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 device. The sharps prevention feature was fully tested to the FDA's guidance document as demonstrated in the performance testing. The addition of the Indications for Use for the gentleheel® Adult Incision Device is for lancing the fingertip area of adults which was demonstrated under clinical use testing.