July 21, 2021

CHIRANA T. Injecta
℅ Nathan Wright
Engineer & Regulatory Specialist
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K201009
Trade/Device Name: CHIRAVAC™ Blood Collection Needles
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA, FMI
Dated: June 16, 2021
Received: June 21, 2021

Dear Nathan Wright:

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,

Payal Patel
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K201009

Device Name
CHIRAVAC™ Blood Collection Needles

Indications for Use *(Describe)*
The CHIRAVAC™ Blood Collection Needles are single use and are intended for venous blood collection in connection with blood collection tubes.

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.

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K201009 - 510K SUMMARY

Submitter's Name:	CHIRANA T. Injecta
Submitter's Address:	Nám. Dr. Schweitzera 194 Stará Turá 916 01 Slovak Republic
Submitter's Telephone:	421-32-770-9972
Contact Person:	Nathan Wright, MS Empirical Testing Corp. 719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	July 14, 2021
Trade or Proprietary Name:	CHIRAVAC™ Blood Collection Needles
Common or Usual Name:	Blood specimen collection device
Classification:	Class II per 21 CFR §862.1675
Product Code:	JKA, FMI
Classification Panel:	Office of In Vitro Diagnostics and Radiological Health

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The CHIRAVAC™ Blood Collection Needles consists of a double-ended hollow stainless steel thin-walled cannula, a threaded polypropylene hub, a sleeve that interrupts blood flow between filling multiple tubes, and polypropylene caps. The device is single use and supplied sterile (ethylene oxide sterilized). The stainless steel cannula and silicone cannula lubricants are classified as externally communicating with limited (≤24 hours) duration contact; all other device components have no contact with patient blood, tissue, or skin. Once the vein has been accessed by puncturing with the intravenous end of the cannula, the healthcare professional will begin the blood collection process by placing evacuated blood collection tubes on the cannula's non-patient end, where the sleeve acts as a non-return valve and allows for more than one tube to be used to collect blood from the vein puncture.

Table 5-1 CHIRAVAC™ Blood Collection Needles

Size Metric (mm)	Size (G x ")	Color Code	Pieces per Box (pcs)	Pieces per Case (pcs)	Item Code
0.6x25	23G x 1"	Blue	100	1 000	CHBCN23100
0.6x38	23G x 1.5"	Blue	100	1 000	CHBCN23112
0.7x25	22G x 1"	Black	100	1 000	CHBCN22100
0.7x38	22G x 1.5"	Black	100	1 000	CHBCN22112
0.8x25	21G x 1"	Green	100	1 000	CHBCN21100
0.8x38	21G x 1.5"	Green	100	1 000	CHBCN21112
0.9x25	20G x1"	Yellow	100	1 000	CHBCN20100
0.9x38	20G x 1.5"	Yellow	100	1 000	CHBCN20112
1.2x25	18G x 1"	Pink	100	1 000	CHBCN18100
1.2x38	18G x 1.5"	Pink	100	1 000	CHBCN18112

INDICATIONS FOR USE

The CHIRAVAC™ Blood Collection Needles are single use and are intended for venous blood collection in connection with blood collection tubes.

The indications for use for the CHIRAVAC™ Blood Collection Needles are similar to the indications of the listed predicate devices.

	Subject	**Predicate**
	CHIRAVAC™ Blood Collection Needles (Subject - K201009)	**Sol-M Blood Collection Needles, Sol-Care Safety Blood Collection Needles, Sol-Care Safety Blood Collection Needle with Holder, Sol-M Blood Collection Set (K182146)**
Indications for Use	The CHIRAVAC™ Blood Collection Needles are single use and are intended for venous blood collection in connection with blood collection tubes.	The Blood Collecting Needle is intended to be used with vacuum blood collection tube for the collection of venous blood. The Safety Blood Collecting Needle is intended to be used with vacuum blood collection tube for the collection of venous blood. The safety shield is intended to aid in the protection against accidental needle stick injury. The Blood Collecting Set with Holder is intended to be used with vacuum blood collection tube for the collection of venous blood.

Discussion of differences in Indications for Use Statements

The subject and predicate device have the same indication for use in collection of blood from the veins. In addition to their blood collection needles, the predicate offers safety blood collecting needles and a blood collecting set with holder with particular indications for those devices that do not apply to the subject.

TECHNICAL CHARACTERISTICS COMPARISON

The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are similar between the subject and predicates:

- Indications for Use
- Sizes
- Materials of manufacture
- Principles of Operations

Table 5-2: Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K182146	Sol-M Blood Collection Needles, Sol-Care Safety Blood Collection Needles, Sol-Care Safety Blood Collection Needle with Holder, Sol-M Blood Collection Set	Sol-Millennium Medical, Inc.	Primary

Table 5-3: Predicate Comparison (CHIRAVAC™ Blood Collection Needles)

	CHIRAVAC™ Blood Collection Needles (Subject - K201009)	**Sol-M Blood Collection Needles, Sol-Care Safety Blood Collection Needles, Sol-Care Safety Blood Collection Needle with Holder, Sol-M Blood Collection Set (K182146)**	**Discussion/ Comment**
Regulation Number	21 CFR § 880.5570	21 CFR § 880.5570	Same
Classification Name	Needle, Hypodermic, Single-Lumen	Needle, Hypodermic, Single-Lumen	Same
Regulatory Class	Class II	Class II	Same
Product Code	JKA, FMI	FMI	Same. JKA is current product code for blood collection needles.
Intended Use/Indications for Use	The CHIRAVAC™ Blood Collection Needles are single use and are intended for venous blood collection in connection with blood collection tubes.	The Blood Collecting Needle is intended to be used with vacuum blood collection tube for the collection of venous blood. The Safety Blood Collecting Needle is intended to be used with vacuum blood collection tube for the collection of venous blood. The safety shield is intended to aid in the protection against accidental needle stick injury. The Blood Collecting Set with Holder is intended to be used with vacuum blood collection tube for the collection of venous blood.	Similar
Principles of Operation	Needles accesses the vein by puncturing with the intravenous end of the cannula. With the non-patient end of the cannula attached to the blood collection tube, the blood is drawn via the piston vacuum into the syringe. The sleeve acts as a non-return valve.	The blood collection devices form a channel between patient's vein and the vacuum blood collection tube which draw the blood to the blood collection tube.	Same
Color Coding	Pink – 18G Yellow – 20G Green – 21G Black – 22G Blue – 23G	Pink – 18G Yellow – 20G Green – 21G Black – 22G Blue – 23G	Same
Single Use?	Yes	Yes	Same
Cannula Material	304 Stainless Steel	Stainless Steel	Same
Other Needle Materials	Polypropylene (needle hub and protective caps), rubber (sleeve), glue.	Polypropylene; Dialyzing Paper; Glue; Rubber	Same. Predicates include safety shields with dialyzing paper. The subject does not have dialyzing paper and does not require a safety shield because it comes with a protective cap which is removed prior to use.
Cannula Lubricant	Silicone Oil	Silicone Oil	Same
Cannula Length	1", 1.5"	5/8", ¾", 1", 1.25", 1.5", 1.75", 2"	Same; additional lengths offered by predicate not offered by subject.

	CHIRAVAC™ Blood Collection Needles (Subject - K201009)	Sol-M Blood Collection Needles, Sol-Care Safety Blood Collection Needles, Sol-Care Safety Blood Collection Needle with Holder, Sol-M Blood Collection Set (K182146)	Discussion/ Comment
Cannula Gauge	18G, 20G, 21G, 22G, 23G	18G, 19G, 20G, 21G, 22G, 23G, 25G	Same; additional gauges offered by predicate not offered by subject.
Biocompatibility	Per ISO 10993	Per ISO 10993	Same
Sterility	Ethylene Oxide to SAL of 10^{-6}	Ethylene Oxide to SAL of 10^{-6}	Same

Discussion of differences in Technological characteristics.

- The predicate device includes safety shields with dialyzing paper. The subject does not require a safety shield because it comes with a protective cap which is removed prior to use and therefore does not have dialyzing paper like the predicates.
- All subject sizes (cannula lengths and gauge options) are sizes available by the predicates; however, not all sizes offered by the predicates are available in the subject needles.

PERFORMANCE TESTING SUMMARY

The CHIRAVAC™ Blood Collection Needles have been tested in the following test modes:

A. Performance Testing – Bench

- ISO 7864:2016 – Sterile hypodermic needles for single use-Requirements and test methods.
    - Color Coding
    - Size Designation
    - Cleanliness
    - pH Limits
    - Limits of Extractable Metals
    - Inspection of Needle Length
    - Inspection of Defects
    - Inspection of Lubrication
    - Needle/Hub Bond Strength
    - Lumen Patency
    - Fragmentation
    - Inspection of Needle Sharpness/Cleanness
    - Penetration Force Test
- ISO 6009:2016 - Hypodermic needles for single use.
    - Color coding
- ISO 9626: 2016 - Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods
    - pH Limits

    - Inspection of Surface Appearance
    - Inspection of Tubing Dimensions
    - Stiffness Test
    - Breakage Resistance Test
    - Corrosion Resistance Test
- Internal Procedure SOP 4113
    - Visual Inspection of Labeling
- Internal Procedure SOP 4401
    - Inspection of Blister/Label Perforation,
    - Vacuum Function Evaluation
    - Test for Rubber Sleeve Returning to Original Position without Damage from Repeated Use
- Internal Procedure SOP 4405
    - Inspection of Cannula Transparency
    - Cleanliness

B. Biocompatibility

The stainless steel cannula and silicone cannula lubricants are classified as externally communicating with limited (≤24 hours) duration contact; all other device components have limited (≤24 hours) duration surface contact with intact skin of the health care professional user and the patient.

- Cytotoxicity per ISO 10993-5 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity.
- Sensitization per ISO 10993-10 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
- Irritation per ISO 10993-10 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
- Acute Systemic Toxicity per ISO 10993-11 Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
- Hemocompatibility per ASTM F756 Standard Practice for Assessment of Hemolytic Properties of Materials
- Material Mediated pyrogenicity per European Pharmacopoeia 10.0 Article 2.6.8 Pyrogens

C. Sterilization, Shipping and Shelf-life

- Packaging integrity test per internal procedures
- Sterile Barrier Packaging test done per ISO 7886-1 Sterile hypodermic syringes for single use – Part 1: Syringes for manual use
- Shelf life of 5 years – validated by accelerated aging per ASTM F1980 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

CONCLUSION

The overall technology characteristics and testing performance data lead to the conclusion that the CHIRAVAC™ Blood Collection Needles are substantially equivalent to the legally marketed predicate device.