November 3, 2023

Koru Medical Systems
Emily DiMambro
Senior Regulatory Affairs Specialist
100 Corporate Dr
Mahwah, New Jersey 07430

Re: K231918
Trade/Device Name: Freedom60 Infusion Pump; High-Flo Subcutaneous Needle Sets; Precision Flow Rate Tubing; High-Flo Super26 Subcutaneous Needle Sets; Freedom60 Pre-Filled Syringe Adapter
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion pump
Regulatory Class: Class II
Product Code: FRN, PKP, FPA
Dated: October 5, 2023
Received: October 5, 2023

Dear Emily DiMambro:

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.

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,

Jake K. Lindstrom -S

Jake Lindstrom, Ph.D.
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.*

Submission Number *(if known)*

Device Name

Freedom60 Infusion Pump;
High-Flo Subcutaneous Needle Sets;
Precision Flow Rate Tubing;
High-Flo Super26 Subcutaneous Needle Sets;
Freedom60 Pre-Filled Syringe Adapter

Indications for Use *(Describe)*

The Freedom60 Infusion System is specifically indicated for the subcutaneous infusion of the following human plasma-derived immunoglobulins when used according to the FDA approved biologic labeling: Cutaquig®, Immune Globulin Subcutaneous (Human) 16.5% Solution (manufactured by Octapharma®); Cuvitru®, Immune Globulin Infusion (Human) 20% (manufactured by Takeda®); Gammagard Liquid®, Immune Globulin Infusion (Human) 10% (manufactured by Takeda®); Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®); and Xembify®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by Grifols®) in the home, hospital, or ambulatory settings when administered according to the approved biologic or drug product labeling.
The Freedom60 Infusion System with the Freedom60® Infusion Pump and Precision Flow Rate Tubing™, is specifically indicated for the intravenous infusion of the following antibiotics when used according to the FDA approved drug product labeling: ertapenem, meropenem, oxacillin, and tobramycin.

The Freedom60 Infusion System consists of the following devices:
- Freedom60® Infusion Pump
- Precision Flow Rate Tubing
- High-Flo Subcutaneous Needle Sets
- HigH-Flo Super26™ Subcutaneous Needle Sets are specifically indicated for the subcutaneous infusion of the following human plasma-derived immunoglobulins: Cutaquig®, Immune Globulin Subcutaneous (Human) 16.5% Solution (manufactured by Octapharma®); Cuvitru®, Immune Globulin Infusion (Human) 20% (manufactured by Takeda®); Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®); and Xembify®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®)

The Freedom60 Infusion System is indicated for use with the following syringes:
• BD® 50 ml syringe
• Medline® 60 ml Syringe
• Hizentra® 50 ml Prefilled Syringe

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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# 510(k) Summary

Prepared on: 2023-06-29

## Contact Details

21 CFR 807.92(a)(1)

| | |
|---|---|
| Applicant Name | Koru Medical Systems |
| Applicant Address | 100 Corporate Dr. Mahwah NJ 07430 United States |
| Applicant Contact Telephone | 240-506-3474 |
| Applicant Contact | Ms. Emily DiMambro |
| Applicant Contact Email | edimambro@korumedical.com |

## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | Freedom60 Infusion Pump;<br>High-Flo Subcutaneous Needle Sets;<br>Precision Flow Rate Tubing;<br>High-Flo Super26 Subcutaneous Needle Sets;<br>Freedom60 Pre-Filled Syringe Adapter |
| Common Name | Infusion Pump |
| Classification Name | Pump, Infusion |
| Regulation Number | 880.5725 |
| Product Code | FRN |

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K200176 | FREEDOM Integrated Syringe Infusion System | FRN |

## Device Description Summary

21 CFR 807.92(a)(4)

The Freedom60 Infusion System is a non-powered infusion system that includes a mechanical infusion pump, subcutaneous needle sets, and tubing sets. The infusion pump exerts a constant force on the syringe plunger to push the medication through the tubing. The tubing set and needle set produce a certain amount of resistance, which moderates the flow rate. The tubing sets and needle sets are provided in a range of sizes and device options (number of needle legs, needle gauge, tubing diameter, etc). The healthcare provider prescribes the tubing/needle sets based on the intended flow rate and dosage of the drug being administered.

The infusion pump is compatible with specific syringe types. An adapter is included as part of this submission to enable compatibility with certain pre-filled syringes. The syringes that are compatible for use with the Freedom60 infusion system are the BD 50ml syringe, the Medline 60 ml syringe, and the Hizentra 50 ml pre-filled syringe.

The infusion pump and pre-filled syringe adapter are reusable. The infusion sets are single use and are terminally sterilized via gamma radiation. The Freedom60 Infusion System is manufactured from materials with an established history of biological safety, and is not manufactured with latex or natural rubber.

## Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Freedom60 Infusion System is specifically indicated for the subcutaneous infusion of the following human plasma-derived immunoglobulins when used according to the FDA approved biologic labeling: Cutaquig®, Immune Globulin Subcutaneous (Human) 16.5% Solution (manufactured by Octapharma®); Cuvitru®, Immune Globulin Infusion (Human) 20% (manufactured by Takeda®); Gammagard Liquid®, Immune Globulin Infusion (Human) 10% (manufactured by Takeda®); Hizentra®, Immune Globulin Subcutaneous

(Human) 20% Liquid (manufactured by CSL Behring®); and Xembify®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by Grifols®) in the home, hospital, or ambulatory settings when administered according to the approved biologic or drug product labeling.
The Freedom60 Infusion System with the Freedom60® Infusion Pump and Precision Flow Rate Tubing™, is specifically indicated for the intravenous infusion of the following antibiotics when used according to the FDA approved drug product labeling: ertapenem, meropenem, oxacillin, and tobramycin.

The Freedom60 Infusion System consists of the following devices:
- Freedom60® Infusion Pump
- Precision Flow Rate Tubing
- High-Flo Subcutaneous Needle Sets
- HigH-Flo Super26™ Subcutaneous Needle Sets are specifically indicated for the subcutaneous infusion of the following human plasma-derived immunoglobulins: Cutaquig®, Immune Globulin Subcutaneous (Human) 16.5% Solution (manufactured by Octapharma®); Cuvitru®, Immune Globulin Infusion (Human) 20% (manufactured by Takeda®); Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®); and Xembify®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring®)

The Freedom60 Infusion System is indicated for use with the following syringes:
• BD® 50 ml syringe
• Medline® 60 ml Syringe
• Hizentra® 50 ml Prefilled Syringe

## Indications for Use Comparison 21 CFR 807.92(a)(5)

The following changes have been made to the indications for use in comparison to the predicate devices:
1) The Hizentra 50ml Prefilled Syringe and Medline 60 ml syringe have been added as compatible syringes.
2) Minor changes have been made to product nomenclature.
The changes do not constitute a new intended use. The Hizentra 50 ml Prefilled Syringe contains the same drug product as previously indicated for use with the predicate Freedom Infusion System, and the Medline 60 ml syringe is intended for the same use as the previously indicated BD 50 ml syringe. No new drug products have been added to the indications for use. The device will continue to be used for subcutaneous or intravenous infusion of the same medicinal products as the predicate device.

## Technological Comparison 21 CFR 807.92(a)(6)

The subject device has the same technological characteristics as the predicate device. There have been no significant changes to the Freedom60 Infusion Pump, Precision Flow Rate Tubing, High-Flo Subcutaneous Needle Sets, and Super26 Subcutaneous Needle Sets from the predicate submission. The only modification to the system is the addition of a removable, optional adapter which is inserted into the Freedom60 Infusion Pump to enable compatibility with a pre-filled syringe. Additional syringes have been verified as compatible with the system when used in the same manner as the predicate device.

## Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following testing was performed in support of the modified device:
- Flow rate verification
- Reliability/use life verification
- Dose accuracy and fitment
- Human factors validation (per IEC 62366-1 and "Applying Human Factors and Usability Engineering to Medical Devices" Guidance)

Additional justification was provided for previously submitted testing which is applicable to the subject device.

Clinical testing is not applicable for this submission.

All verification and validation testing was successfully completed. The non-clinical testing performed demonstrates that the device is as safe and effective as the legally marketed predicate device, and demonstrates that the device meets the performance requirements set out as part of the design control process. Additional justification was provided for previously conducted testing which supports the modified device.