October 14, 2025

Keter Canada, Inc.
℅ Trey Thorsen
Regulatory Consultant
The FDA Group
290 Turnpike Road
Suite 200
Westborough, Massachusetts 01581

Re: K252637
Trade/Device Name: Community Containers (Flap and Daisy)
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: MMK
Dated: August 20, 2025
Received: August 20, 2025

Dear Trey Thorsen:

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,

Stephen A. Anisko -S

Digitally signed by Stephen A. Anisko -S
Date: 2025.10.14 08:52:47 -04'00'

Stephen Anisko
Acting Assistant Director
DHT4C: Division of Infection Control 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.

510(k) Number *(if known)*
K252637

Device Name
Community Containers (Flap and Daisy)

Indications for Use *(Describe)*
The Community Container (Flap and Daisy) are intended to be used for the collection, transportation and disposal of 1 ml and 2 ml hypodermic needles and syringes in health care areas, home care environment and any other area requiring the use of sharps containers for the collection, transportation and disposal of used 1 ml and 2 ml hypodermic needles and syringes.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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
K252637

October 13, 2025

I. SUBMITTER

Keter Canada, Inc.
205 Market Dr,
Milton, ON L9T 4Z7, Canada
Contact: Lovleen Kaur
Email: Lovleen.kaur@keter.com
Phone: 289-409-9133

II. CORRESPONDANT

The FDA Group
290 Turnpike Road
Suite 200
Westborough, Massachusetts 01581
Contact: Trey Thorsen
Email: athorsen@the-fda-group.com
Phone: 850-450-3932

III. DEVICE

Name of Device: Community Containers (Flap and Daisy)
Common or Usual Name: Container Sharps
Classification Name: Hypodermic single lumen needle 21 CFR 880.5570
Product Code: MMK
Device Class: II

IV. PREDICATE DEVICE

Name of Device: ASP HealthCare Fitpack Product Line cleared via K060037.
Common or Usual Name: Container Sharps
Classification Name: Hypodermic single lumen needle 21 CFR 880.5570
Product Code: MMK
Device Class: II

V. INDICATIONS FOR USE

The Community Containers (Flap and Daisy) are intended to be used for the collection, transportation and disposal of 1 ml and 2 ml hypodermic needles and syringes in health care areas, home care environment and any other area requiring the use of sharps containers for the collection, transportation and disposal of used 1 ml and 2 ml hypodermic needles and syringes.

VI. DEVICE DESCRIPTION

The Community Containers (Flap and Daisy) are portable molded polypropylene syringe collectors that provide an alternate to re-sheathing a needle with its original protective cover and are designed to safely hold small low volume sharps such as blood needles, lancets, and small syringes.

The Community Containers (Flap and Daisy) are single use, non-sterile disposable, transportable sharps collectors intended to be used for the collection, transportation and disposal of 1 ml and 2 ml hypodermic needles and syringes in health care areas, home care environment and any other area requiring the use of sharps containers for the collection, transportation and disposal of used 1 ml and 2 ml hypodermic needles and syringes.

The Community Containers (Flap and Daisy) are rectangular, with a conical taper and a temporary closure capability, which can be reopened for the storage of additional sharps prior to terminal disposal.

The Community Containers (Flap and Daisy) are approximately 8.7cm (L) x 4.3cm (W) x 15.1cm (H). The cap is opaque plastic with a hinged cap, which can be snapped closed to contain the biohazardous sharps. Each Community Container is individually embossed with a biohazard symbol.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Both the Community Containers (Flap and Daisy) and the predicate device are portable, transportable sharps container, with a temporary closure system which protects the end user prior to incineration.

The subject and predicate device are rectangular with a conical taper and a temporary closure capability, which can be reopened for the storage of additional sharps prior to terminal disposal.

Element	**Subject Device**	**Predicate Device**	**Discussion of Differences**
510(k) Number	**K252637**	**K060037**	
Device Name	**Community Containers (Flap and Daisy)**	**ASP HealthCare Fitpack Product Line**	
Device Classification	21 CFR §880.5570: Class II	21 CFR §880.5570: Class II	No difference.
Product Code	MMK – Container Sharps	MMK – Container Sharps	No difference.
Device Common Name as Cleared by FDA	Container, Sharps	Container, Sharps	No difference.
Intended / Indications for use	The Community Containers (flap and daisy) are intended to be used for the collection, transportation and disposal of I ml and 2 ml hypodermic needles and syringes in health care areas, home care environment and any other	The Product is intended to be used for the collection, transportation and disposal of 1 ml and 2 ml hypodermic needles and syringes in health care areas, home care environment and any other area requiring the use of	No difference.

Element	Subject Device	Predicate Device	Discussion of Differences
510(k) Number	**K252637**	**K060037**	
Device Name	**Community Containers (Flap and Daisy)**	**ASP HealthCare Fitpack Product Line**	
	area requiring the use of sharps containers for the collection, transportation and disposal of used I ml and 2 ml hypodermic needles and syringes.	sharps containers for the collection, transportation and disposal of used 1 ml and 2 ml hypodermic needles and syringes.	
Device Description	The Community Containers (Flap and Daisy) are compact, injection molded containers complete with integral molded lid. Specifically designed for personal storage, collection, transportation and disposal of 1ml hypodermic needles and syringes. Ideal for front line health workers, diabetics, in healthcare areas, home care environments and any other area requiring the use of sharps containers.	Compact high quality injection molded container complete with integral molded lid. Specifically designed for personal storage, collection, transportation and disposal of 1ml hypodermic needles and syringes. Ideal for front line health workers, diabetics, in healthcare areas, home care environments and any other area requiring the use of sharps containers.	No difference.
Size (volume)	325mL nominal	130mL – 750mL	No difference. The predicate device volume is within the volume range cleared in K060037.
Dimension (cm) (L x W x H)	8.7 x 4.3 x 15.1	8.1 x 3.8 x 15.3	Similar. The subject device's dimensions are comparable to those of the predicate. The subject device is still considered a pocket sharps container as defined by ISO 23907-1:2019.
Single Use	Yes	Yes	No difference.
Rx or OTC	OTC	OTC	No difference.
Environment of Use	Health care areas, home care environment and any other area requiring the use of sharps containers for the collection, transportation and disposal of used I ml and 2 ml	Health care areas, home care environment and any other area requiring the use of sharps containers for the collection, transportation and disposal of used 1 ml and 2	No difference.

Element	Subject Device	Predicate Device	Discussion of Differences
510(k) Number	K252637	K060037	
Device Name	Community Containers (Flap and Daisy)	ASP HealthCare Fitpack Product Line	
	hypodermic needles and syringes.	ml hypodermic needles and syringes.	
Application	Specifically designed for personal storage, collection, transportation and disposal of used 1 ml and 2 ml hypodermic needles and syringes.	Specifically designed for personal storage, collection, transportation and disposal of used 1 ml and 2 ml hypodermic needles and syringes.	No difference.
Material	Polypropylene	Polypropylene	No difference.
Sharps Access	Top opening	Top opening	No difference.
Sharps Closure	Hinged closure	Hinged closure	No difference.
Configuration	• Divider Flap • Daisy Top	• Divider Flap • Daisy Top	No difference.
Impact and leak resistance	Yes	Yes	No difference.
Needle Penetration Resistance-	Yes	Yes	No difference.
Non-Sterile	Yes	Yes	No difference.
Color	Multiple colors	Black or Yellow.	Similar. While the predicate comes in only two colors, the subject device comes in multiple colors depending on the customers preference.
Method of Manufacture	Injection molding	Injection molding	No difference

VIII. NON-CLINICAL TESTING SUMMARY

Performance Testing

The Community Containers (Flap and Daisy) were designed using ISO 23907-1:2019 Sharps injury protection — Requirements and test methods-Sharps containers Part 1: Single-use sharps containers, and its size of 0.3L qualifies it as a pocket collector as defined by the standard. It is designed for storage of such sharps as blood needles, lancets, and small syringes prior to terminal disposal. The Community

Containers (Flap and Daisy) meet the performance requirements for the standard. In addition, it has also been tested by an independent laboratory to meet the requirements for puncture.

Test	Acceptance Criteria	Result	Comment
Resistance to Penetration	The force needed to penetrate the test specimens shall be: • A minimum of 16 N. • A minimum average of 18 N.	19.04 N minimum	All samples tested met the acceptance criteria. The minimum average of all samples complied with the acceptance criterion.
Resistance to Spillage by Toppling	There shall be no evidence of a breach of the sample containment area. Five (5) minutes after toppling: • There shall be no evidence that the function of the container has been compromised. • The temporary closure must remain intact	No evidence of leakage	All samples tested met the acceptance criteria.

Animal Studies
No animal data submitted.

Clinical Studies
No clinical data submitted.

IX. CONCLUSIONS

The conclusions drawn for the non-clinical tests demonstrate that the device is as safe, as effective and performs as well as or better than the legally marketed predicate device, K060037.