September 14, 2021

Nitta M&T (Thailand) Co., Ltd.
% Vaibhav Rajal
Official Correspondent for Nitta M&T (Thailand) Co., Ltd.
mdi Consultants Inc.
55 Northern Blvd, Suite 200
Great Neck, New York 11021

Re: K211464
Trade/Device Name: Nitta M&T Safety Box
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic single lumen needle
Regulatory Class: Class II
Product Code: MMK
Dated: August 4, 2021
Received: August 4, 2021

Dear Vaibhav Rajal:

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,

Clarence W. Murray, III, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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)*
K211464

Device Name
Nitta M&T Safety Box

Indications for Use *(Describe)*
Nitta M&T Safety Boxes are intended to provide a receptacle for used, contaminated medical sharps and act as an enclosure during transport to ultimate disposal. The device is intended to be used for safe disposal of hazardous sharps such as hypodermic needles, syringes, lancets, and blood needles by qualified personnel in health care facilities and other facilities in which medical sharps may be used. The device is not in contact with or available to the patient in normal use.

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.

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Nitta M&T

Nitta M&I (Thailand) Co., Ltd.
19/52 Unit G5, Phaholyothin Rd., Moo 10
Khlong Nueng, Khlong Luang Pathumthani 12120 Thailand

General Specifications Table

Model No.	Weight(g)	Capacity (Total) ml	Capacity (Full line)	Dimensions of goods (mm) (L x W x H)	Colors
NT-001*/**	149	1,000	735	113 x 109 x 135	Red / Yellow
NT-002*/**	210	1,970	1,490	151 x 150 x 137	Red / Yellow base and transparent lid
NT-003*/**	441	3,350	2,780	132 x 246 x 198	Red / Yellow base and transparent lid
NT-004*	563	5,060	3,750	136 x 279 x 210	Red / Yellow
NT-005*/**	660	8,015	6,750	132 x 246 x 400	Red / Yellow base and transparent lid
NT-006*/**	456	3,350	2,500	136 x 235 x 210	Red / Yellow base and transparent lid
NT-007*/**	674	8,015	6,750	136 x 245 x 422	Red / Yellow base and transparent lid
NT-008	48g	210	160	78 x 50 x 82	Red / Yellow

* Intended to be used in areas where there is no unsupervised patient access.

** Intended for use with mounting accessories.

Model No.	Lid configuration	Locking mechanism	Dimensions of aperture (mm)	Needle unwinder	Mounting Accessories
NT-001	Opening Hinge	Hinged closure	45 x 38	Luer slip and luer lock needle unwinder, and Pen-needle unwinding port are in the lid and above the containment area.	A) Freestanding B) Rubber Stabilizer C) Metal pole mounting bracket D) Metal hook bracket
NT-002	Opening Hinge	Hinged closure	106 x 41.6		A) Freestanding B) Rubber Stabilizer C) Metal pole mounting bracket D) Metal hook bracket
NT-003	Opening Hinge	Hinged closure	185 x 44.8		A) Freestanding B) Lockable wall mount cabinet C) Metal pole mounting bracket D) Metal hook bracket
NT-005	Opening Hinge	Hinged closure	185 x 44.8		A) Freestanding B) Rubber Stabilizer C) Metal pole mounting bracket

					D) Metal hook bracket
NT-004	Opening Hinge	Hinged closure	240 x 55.8	Luer slip and luer lock needle unwinder is in the lid and above the containment area.	A) Freestanding
NT-006	Counter Balance	Counter Balance	198 x 55	n/a	A) Freestanding B) Lockable wall mount cabinet C) Metal pole mounting bracket D) Metal hook bracket
NT-007	Counter Balance	Counter Balance	198 x 55	n/a	A) Freestanding B) Rubber Stabilizer C) Metal pole mounting bracket D) Metal hook bracket
NT-008	Opening Hinge	Hinged closure	n/a	Pen-needle unwinding port is in the lid and above the containment area.	A) Freestanding

Accessories

Nitta M&T offers several mounting accessories for own sharps containers.

Manufacture	Part Number	Description
SARAYA	77251 1L Rubber stands	Table top Rubber Stabilizer of NT-001
SARAYA	77248 1L SS pole bracket	Holding bracket for pole mounting of NT-001
SARAYA	77256 1L SS hook type bracket	Hook type bracket of NT-001
FINEPRO	77252 1.5L Rubber stand	Table top Rubber Stabilizer of NT-002
SARAYA	77249 1.5L SS pole bracket	Holding bracket for pole mounting of NT-002
SARAYA	77257 1.5L SS hook type bracket	Hook type bracket of NT-002
SARAYA	77250 3.2L/7.6L SS pole bracket	Table top Rubber Stabilizer of NT-003, NT-005, NT-006, NT-007
SARAYA	77258 3.2L/7.6L SS hook type bracket	Holding bracket for pole mounting of NT-003, NT-005, NT-006, NT-007
Nitta M&T	NT-010 3.2L Lockable wall mount cabinet	Lockable wall mounting cabinet of NT-003, NT-006
Nitta M&T	NT-016 Rubber Stabilizer for 3.2L/7.6L Safety Box	Table top Rubber Stabilizer of NT-003, NT-005, NT-006, NT-007
Nitta M&T	NT-017 7.6L Lockable wall mount cabinet	Lockable wall mounting cabinet of NT-005,007

Nitta M&T (Thailand) Co., Ltd.
19/52 Unit G5, Phaholyothin Rd., Moo 10
Khlong Nueng, Khlong Luang Pathumthani 12120 Thailand

510(k) Summary

The assigned 510(k) number is K211464

1. **Submitter's Identification:**

Nitta M&T (Thailand) Co., Ltd.
19/52 Unit G5, Phaholyothin Road, Moo 10 Khlong Hueng
Khlong Luang Pathumthani, 12120 Thailand.

Date: July 28, 2021

Contact: Mr. Mamiko Oshiro
Nitta M&T (Thailand) Co., Ltd.
19/52 Unit G5, Phaholyothin Road, Moo 10 Khlong Hueng
Khlong Luang Pathumthani, 12120 Thailand
Email: osiromamiko@nittamold.com

2. **Name of the Device:**

Nitta M&T Safety Box

Regulation Description: Hypodermic single lumen needle.
Product Code: MMK
Regulation Number: 880.5570
Device Class: II

3. **Information on Predicate Devices:**

Predicate Device:

- Trade/Device Name: North American Rescue Sharps Shuttle
- Regulation Number: 21 CFR 880.5570
- Regulation Name: Hypodermic Single Lumen Needle
- Regulatory Class: Class II
- Product Code: MMK

Second Predicate Device:

- Trade/Device Name: Tiger Sharps Containers
- Regulation Number: 21 CFR 880.5570
- Regulation Name: Hypodermic Single Lumen Needle
- Regulatory Class: Class II
- Product Code: MMK

4. Indications for Use Statement:

Nitta M&T Safety Boxes are intended to provide a receptacle for used, contaminated medical sharps and act as an enclosure during transport to ultimate disposal. The device is intended to be used for safe disposal of hazardous sharps such as hypodermic needles, syringes, lancets, and blood needles by qualified personnel in health care facilities and other facilities in which medical sharps may be used. The device is not in contact with or available to the patient in normal use.

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NT-008	48g	210	160	78 x 50 x 82	Red / Yellow

* Intended to be used in areas where there is no unsupervised patient access.

** Intended for use with mounting accessories.

Model No.	Lid configuration	Locking mechanism	Dimensions of aperture (mm)	Needle unwinder	Mounting Accessories
NT-001	Opening Hinge	Hinged closure	45 x 38	Luer slip and luer lock needle unwinder, and Pen-needle unwinding port are in the lid and above the containment area.	A) Freestanding B) Rubber Stabilizer C) Metal pole mounting bracket D) Metal hook bracket
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NT-008	Opening Hinge	Hinged closure	n/a	Pen-needle unwinding port is in the lid and above the containment area.	A) Freestanding

Accessories

Nitta M&T offers several mounting accessories for own sharps containers.

Manufacture	Part Number	Description
SARAYA	77251 1L Rubber stands	Table top Rubber Stabilizer of NT-001
SARAYA	77248 1L SS pole bracket	Holding bracket for pole mounting of NT-001
SARAYA	77256 1L SS hook type bracket	Hook type bracket of NT-001
FINEPRO	77252 1.5L Rubber stand	Table top Rubber Stabilizer of NT-002

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Nitta M&T	NT-017 7.6L Lockable wall mount cabinet	Lockable wall mounting cabinet of NT-005,007

5. Device Description:

Nitta M&T Safety Boxes are disposable and non-sterile sharps containers. The base container and its lid are made of puncture resistant, leak proof polypropylene. These containers are offered in various volumes, sizes, and lid styles. Mounting accessories (brackets) are available for use with 1.0L, 1.5L, 3.2L and 7.6L containers in locking and non-locking variations. Equipped with visible final lock mechanism. A design that allows you to determine and clearly differentiate the permanent and temporary closure engagement by the position of final lock claws.

Device Parts:

Parts & Accessories	Product	Material	Patient Contact (Direct/Indirect)?
Lid	All	Polypropylene	No
Base	All	Polypropylene	No
Lever	NT-001 / NT-002 / NT-003 / NT-004 / NT-005 / NT-008	ABS	Yes

6. Technological Characteristic Comparison Table:

Characteristic	Submitted Subject Device	Predicate Device	Second Predicate Device	Comparison
510(k)	NA	K152340	K190240	n/a
Device Name	Nitta M&T Safety Box	North American Rescue Sharps Shuttle	Tiger Sharps Containers	
Product code	MMK	MMK	MMK	Same
Regulation No.	21 CRF 880.5570	21 CRF 880.5570	21 CRF 880.5570	Same
Class	II	II	II	Same
Size	0.2 / 1L / 1.5L / 3.2L / 5.0L / 7.6L	-	1 Quart / 5 Quart / 2 Gallon / 2 Gallon B / 15 Liter 3 Gallon/ 8 Gallon	Different
Dimensions (mm)	113 x 109 x 135 / 151 x 150 x 137 / 132 x 246 x 198 / 136 x 279 x 210 / 132 x 246 x 400 / 136 x 235 x 210 / 136 x 245 x 422 / 78 x 50 x 82	Approximately 6.41" (H) (163mm) by 1.33" (W I.D.) (34mm)	3.91x3.91x6.37 / 10.60 x4.70x10.64 / 10.84x6.86x10.36 / 10.22x7.02x13.30 / 9.50x14.77x12.03 / 14.86x7.25x14.00 / 10.92x15.61x17.27	Different
Weight range	48-674 g	Approximately 1.5oz	109-1172 g	Different
No. of Pieces	2-6	2-3	2-3	Different
Material	Poly-propylene	Poly-propylene	Poly-propylene	Different
Base Color	Red / Yellow	Non-colored	Red	Different
Clarity	Opaque/translucent	translucent	Opaque/translucent	Different
Method of Manufacture	Injection Molded	Injection Molded	Injection Molded	Same
Performance testing (puncture, impact, drop, stability, integrity)	Pass	Pass	Pass	Same
Standards	ISO23907-1:2019	ISO 23907, ASTM F 2132-01	ISO 23907, ASTM F 2132	Same
Technical characteristics	Refer to statement in Summary of Technological Characteristics section	Refer to statement in Summary of Technological Characteristics section	Refer to statement in Summary of Technological Characteristics section	Yes
Lid configurations / aperture dimensions	Refer to table below in Indication for Use section	Refer to table below in Indication for Use section	Refer to table below in Indication for Use section	Yes
Accessories	Mounting accessories (brackets) are available for use with 1.0L, 1.5L, 3.2L and 7.6L containers in locking and non-locking variations.	Mounting accessories (brackets) are available for use with 1g and 2g containers in locking and non-locking variations.	Mounting accessories (brackets) are available for use with 1qt, 5qt, 2g and 3g containers in locking and non-locking variations.	Different

7. Summary of Non-Clinical Tests:

Performance testing was provided to validate and verify that the subject device met all of the requirements of related international standards, including biocompatibility, sterility, and product specifications. Results of these tests demonstrate the subject device met the acceptance criteria or specification in consensus standards provided below.

Summary of Performance Testing:

Test Objective	Testing Standards	Test method	Performance Results
Container Stability	ISO 23907-1:2019	The sharps containers were filled to fill line with material of a density of (0.20±0.01) Kg/l. Placed the container in the most adverse position on its base for toppling on a surface with a minimum inclination angle of 15°	Meets ISO23907-1:2019 Requirements – No more than 0 failures per container were observed.
Handle Strength	ISO 23907-1:2019	The sharps containers were filled to 150% of the manufacturer's allowable gross mass and were	Meets ISO23907-1:2019 Requirements - No failures were observed.

		then suspended by the handles for a period of at least 60 minutes.	
Puncture resistance	ISO 23907-1:2019	Fix a hypodermic needle of nominal size 0.8mm x 25mm conform to ISO7864 in the needle holder. Place the test specimen centrally on the test specimen support (having 6mm diameter hole) with the inside container surface facing upwards and lower the 21-gauge needle vertically (90°±5°) towards the test specimen at a rate of (100±10) mm/min. Allow the needle to pass through the test specimen and penetration resistance was recorded. Per the acceptance criteria, the average force was required to be minimum of 16 N and an average of 18 N or greater.	Meets ISO23907-1:2019 Requirements - As such, all Nitta M&T products were found to meet the acceptance criteria. Testing resulted minimum force of 18.6 N was observed.
Resistance to Damage (Drop/Impact Test)	ISO 23907-1:2019	Sharps container at (23±5) C or at least 2 h and carry out the test the same temperature. These are designed to conform to specific shipping and transportation requirements such as UN regulations and ADR regulations. Drop tested at height of 1m per test standard.	Meets ISO23907-1:2019 Requirements – No evidence of leakage or damage resulting in a breach of the sharps containment area were observed. As such, all Nitta M&T products were found to meet the acceptance criteria for resistance to damage from a vertical drop.

8. Sterility Information

The subject device container is non-sterile; therefore, no sterility testing was performed.

9. Clinical Testing:

Not Applicable.

10. Conclusion:

The conclusions drawn from the non-clinical performance testing data demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate devices.