March 25, 2021

NeedleSmart Limited
Tom Baker
Research & Development Engineer
Suite 2B, Stanley Grange Business Park, Ormskirk Road,
Knowsley, Prescot, L34 5NB
United Kingdom

Re: K202073
Trade/Device Name: NeedleSmart Professional (NS Pro)
Regulation Number: 21 CFR 880.6210
Regulation Name: Sharps Needle Destruction Device
Regulatory Class: Class II
Product Code: MTV
Dated: February 12, 2021
Received: February 25, 2021

Dear Tom Baker:

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.
Acting 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)*
K202073

Device Name
NeedleSmart Professional (NS Pro)

Indications for Use *(Describe)*
The NeedleSmart Professional (NS Pro) is a needle destruction device that is intended for use by individuals and healthcare professionals to safely destroy 21-25 gauge needles between 0.625 (¾") inches to 1.5 ( l ½") inches i.e. approx. 1.6 cm to 3.8 cm. The device is for use in treatment settings such as treatment rooms, emergency/trauma rooms, wards, and medication rooms of Hospitals and Outpatient Clinics/Medical Offices, Dental Offices, and Clinical Laboratories.

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 – K202073

## 1. Sponsor/ Applicant

NeedleSmart Limited
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United Kingdom

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**Summary Preparation Date**: March 23, 2021

## 2. Device

| | |
|---|---|
| Trade Name | NeedleSmart Professional (NS Pro) |
| Common Name | Sharps Needle Destruction Device |
| Classification Name | Sharps Needle Destruction Device |
| Classification | Class II |
| Product Code | MTV |
| Regulation Number | 21 CFR 880.6210 |
| Review Panel | General Hospital |

## 3. Predicate Device

Sharps Terminator (approved under P120018).
*Note: A Sharps Needle Destruction Device is now regulated under Class 2 and requires a 510(k) submission.*

## 4. Device Description

The NeedleSmart Professional (NS Pro) is a needle destruction device that is intended for use by individuals and healthcare professionals to safely destroy needles. It operates using an internal rechargeable Lithium-ion battery pack which can be recharged using the power supply (wall charger) that is provided with the unit. The device is not intended to be used while connected to the charger.

The NS Pro is activated when the user applies slight downward force on the syringe to insert the needle in the needle aperture disc in the top of the unit. The needle insertion activates a button beneath the insert disc. The needle is then contained by a hard-wearing quartz tube and a current is passed through the tip of the needle, thereby increasing its temperature. Once the needle has been heated to its melting point, it becomes soft and the melted content is collected within a hemispherical electrode. The molten metal gets compressed into a hemispherical 'stub' which is allowed to cool. It is then removed from the device and disposed into a sharps container.

## 5. Indications for Use

The NeedleSmart Professional (NS Pro) is a needle destruction device that is intended for use by individuals and healthcare professionals to safely destroy 21-25 gauge needles between 0.625 (⅝") inches to 1.5 (1½") inches i.e. approx. 1.6 cm to 3.8 cm. The device is for use in treatment settings such as treatment rooms, emergency/trauma rooms, wards, and medication rooms of Hospitals and Outpatient Clinics/Medical Offices, Dental Offices, and Clinical Laboratories.

## 6. Technological Characteristics Comparison

The technological characteristics comparison between the NeedleSmart Professional (NS Pro) and the Sharps Terminator is provided in the following table:

**Table 1: Technological Characteristics Comparison**

| | **Subject Device** | **Predicate Device** | **Comparison** |
|---|---|---|---|
| | **NeedleSmart Professional (NS Pro)** | **Sharps Terminator (approved under P120018)** | |
| | | | |
| Submitter | NeedleSmart Ltd | Sharps Terminator, LLC | |
| Device Classification | Product Code: MTV<br>21 CFR 880.6210 | Product Code: MTV<br>21 CFR 880.6210 | Same |
| Prescription / Over-The-Counter (OTC) Use | Prescription Use | Prescription Use | Same |

| | Subject Device | Predicate Device | Comparison |
|---|---|---|---|
| | **NeedleSmart Professional (NS Pro)** | **Sharps Terminator (approved under P120018)** | |
| | | | |
| Indications for Use | The NeedleSmart Professional (NS Pro) is a needle destruction device that is intended for use by individuals and healthcare professionals to safely destroy 21-25 gauge needles between 0.625 (⅝") inches to 1.5 (1½") inches i.e. approx. 1.6 cm to 3.8 cm. The device is for use in treatment settings such as treatment rooms, emergency/trauma rooms, wards, and medication rooms of Hospitals and Outpatient Clinics/Medical Offices, Dental Offices, and Clinical Laboratories. | This device is indicated for use by individuals and healthcare professionals to safely destroy 18-27 gauge needles up to 2 inches (approx. 5 cm). The device is for use in treatment settings such as treatment rooms, emergency/trauma rooms, wards, and medication rooms of Hospitals and Outpatient Clinics/Medical Offices, Dental Offices, and Clinical Laboratories. | Similar |
| Operating Principle and Description | NS Pro enables single button, one handed operation.<br><br>The electrical heating of needle metal leads to compression of molten metal which is then allowed to cool onto the end of the needle stub that is collected in a quartz tube.<br><br>The unit requires regular clean down and replacement of quartz tube every 3 months | Sharps Terminator enables single button, one handed operation.<br><br>The electrical heating of needle metal produces swarf that is collected in tube<br><br>The unit requires swarf tube to be emptied weekly | Similar |
| Major Parts/ Components | Clamp Electrodes<br>DC Motor<br>Melt Electrode<br>Electrode Carriage Assembly<br>Stepper Motor & Drive Belt System<br>Quartz Tube<br>Operating PCBs | Positive and Negative Electrodes<br>Cutting Blade<br>Swarf Container Collection Tube<br>UV Bulb<br>Operating PCB(s) | Different |

| | Subject Device | Predicate Device | Comparison |
|---|---|---|---|
| | **NeedleSmart Professional (NS Pro)** | **Sharps Terminator (approved under P120018)** | |
| | | | |
| Sterility and Shelf-life | Not provided sterile. No shelf life claimed | Not provided sterile. No shelf life claimed | Same |
| Dimensions | Height x width x depth: 249.6mm x 139.0mm x 144.2mm | Cylindrical construction, approximately 4.5” in diameter and 7” in height. | Different |
| Needle Range | Gauge: 21-25G<br>Length: 0.625” - 1.5” | Gauge: 18-27G<br>Length: Up to 2” | Similar |
| Number of needle melts per Charge | At least 100 (assuming 21G needles that are 1.5” in length) | 40 to over 200 depending on needle gauge and length | Similar |
| Battery Type | Rechargeable<br>7-cell Lithium-Ion (Li-ion) battery pack | Rechargeable<br>Nickel metal hydride (NiMH) battery | Different |
| Battery Rating | 25.2VDC, 3Ah, 75.6Wh | 4.8VDC, 6Ah, 28.8Wh | Different |
| Power Supply (Charger) | Input: 100-240VAC, 50-60Hz<br>Output: 29.4VDC, 0.56A | Not specified | |

The intended use of the NeedleSmart Professional (NS Pro) is same as the intended use of the predicate Sharps Terminator as both are needle destruction devices intended for use by individuals and healthcare professionals to safely destroy needles. The operating principle of the NS Pro and the Sharps Terminator is similar as both are portable devices that use electric current for needle destruction. The devices are activated when the user inserts the needle vertically into the aperture in the top of the units. Both devices support one handed operation with a single button press.

The indications for use differ slightly as the NS Pro is intended to destroy 21-25 gauge needles between 0.625 inches and 1.5 inches (approx. 1.6cm to 3.8cm), whereas, the Sharps Terminator is intended to destroy 18-27 gauge needles up to 2 inches (approx. 5 cm).

With Sharps Terminator, the needle is burned away by an electrode down to the hub as it is inserted into the device. Once the syringe/needle combination is fully seated into the device a secondary cutter activates and chops through the needle hub thereby separating the syringe body from any remaining needle stub. The debris (swarf) left from the needle destruction is collected in the swarf collection tube. In contrast, with NS Pro, the inserted needle is contained in a hard-wearing quartz tube. When

current passes through the tip of the needle, its temperature increases and makes the metal soft. The needle metal melts and is collected within a hemispherical electrode. The molten metal is then compressed and allowed to cool onto the end of the needle stub, which can then be disposed of into a sharps container. The functional capability of the NS Pro to effectively process and destroy needles is validated through comprehensive hardware, firmware, and software testing.

The Sharps Terminator uses rechargeable Nickel metal hydride (NiMH) battery pack whereas; the NS Pro uses a rechargeable Lithium-ion battery pack. The battery packs can be recharged using the power supplies (chargers) provided with these devices. The Sharps Terminator can be used while left plugged into the charger, or used remotely until the battery is discharged. However, the NS Pro is only intended to be used on battery power. The Lithium-ion battery pack used in NS Pro complies with IEC 62133.

The Sharps Terminator is able to destroy between 40 to over 200 needles per charge, depending on needle gauge and length burned. The NS Pro can destroy at least 100 needles per charge, assuming 21G needles that are 1.5” in length. The capability of the NS Pro to destroy at least 100 needles per charge is demonstrated through performance testing.

The dimensions of the NS Pro are different compared to Sharps Terminator. Also, the Sharps Terminator intentionally produces high voltage arcs across connection points, while NS Pro produces low voltage reconnection arcs only as by-process. The electrical safety and electromagnetic compatibility of the NS pro has been tested per standards IEC 61010-1 and EN/ IEC 60601-1-2, respectively. Additionally, the power supply (charger) provided with NS Pro meets the requirements of IEC 60601-1.

## 7. Summary of Non Clinical Performance Testing

The following non-clinical performance tests were conducted to demonstrate electrical safety and Electromagnetic Compatibility, and to validate the hardware, software, and firmware of the NS Pro device.

| Test Objective | Standard | Results and Conclusion |
|---|---|---|
| Electrical Safety evaluation | IEC 61010-1 | Compliance |
| Safety evaluation of Lithium-Ion (Li-ion) battery pack | IEC 62133 | Compliance |
| Electromagnetic Compatibility evaluation | IEC 60601-1-2 | Compliance |
| System Testing – verification of NS Pro initialization, needle melt functionality, needle range specification, battery capacity, service mode settings, charging function, and display (error/ informational screes) | | PASS – demonstrating successful verification and validation of the software |
| Hardware initialization, needle melt hardware checks, and error conditions testing | | PASS – demonstrating successful validation of the hardware and firmware |
| Hardware and firmware inspection testing | | PASS – demonstrating successful validation of the hardware and firmware |

In addition, the following performance bench tests were performed to demonstrate the capability of the NS Pro to destroy (melt) needles.

| Test Objective | Acceptance Criteria | Results and Conclusion |
|---|---|---|
| Evaluate the performance of the NS Pro device to safely and effectively melt a range of hypodermic needles.<br><br>50 needles of each gauge and length combination (total 700 needles) were subjected to the melting process individually using the NS Pro device. | NS Pro device should process needles with success rate of 95% or more | The needle melt success rate was 97.6% which met the acceptance criteria thereby demonstrating the capability of the NS Pro device to safely and effectively destroy hypodermic needles within its specified range. |

| Test Objective | Acceptance Criteria | Results and Conclusion |
|---|---|---|
| Determine whether the NS Pro needle melt process produced harmful or toxic fumes. | There should be no emission of harmful gas in significant enough quantities which is deemed hazardous. | The melt process did not result in emission of harmful gas in a potentially toxic quantity. |
| Determine whether dangerous/ unsafe noise is produced during the operation of the NS Pro. | Maximum recorded noise should be within the acceptable instantaneous limit of 140dB. | Maximum recorded noise during the testing was an instantaneous value of 84.8dB. Therefore, NS Pro did not produce dangerous noise in any cases. |
| Determine whether visible sparking is produced during the operation of the NS Pro | No visible sparks produced external to the device throughout the course of the testing. | The needle melt process was performed 10 times in 5 different NS Pro devices. Visible sparks were not produced in any cases. |
| Virolgoical study – Analysis of potential contamination from pathogenic microorganisms, with the use of NS Pro device | No dangerous viral aerosols produced<br><br>No pathogenic activity detected on the processed needles | The results from first study showed no infectious virus particles (PPV or MuLV) detected in the test sample demonstrating that the NS Pro device operation does not result in emission of infectious aerosols.<br><br>The results from the second study confirmed no pathogenic activity was detected on the processed needles |

**8. Clinical Testing**

The submission does not contain any data from clinical testing.

**9. Conclusion:**

The conclusions drawn from the non-clinical performance tests demonstrate that the NeedleSmart Professional (NS Pro) is as safe, as effective, and performs as well as or better that the legally marketed predicate device, Sharps Terminator.