SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Sharps Needle Destruction Device

Device Trade Name: Sharps Terminator®

Device Procode: MTV

Applicant's Name and Address: Sharps Terminator, LLC
6502 Slide Rd Suite 402
Lubbock, Texas 79424

Correspondent: David C. Furr
FDC Services, LLC
8708 Capehart Cove
Austin, Texas 78733

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P120018

Date of FDA Notice of Approval: February 17, 2016

II. INDICATIONS FOR USE

The Sharps Terminator® product is a stationary or portable needle destruction device that is intended 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.

III. CONTRAINDICATIONS

There are no known contraindications.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the Sharps Terminator labeling.

V. DEVICE DESCRIPTION

The Sharps Terminator® is a portable needle destruction device designed to safely destroy 18-27 gauge needles up to 2 inches (approx. 5 cm) in length attached to syringes 3 – 20 cc. The needle, being a conductor, activates the device and 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," which is to be emptied after 30 device cycles. The Sharps Terminator operates from an internal rechargeable NiMH battery pack. The battery pack can be recharged using the Sharps Terminator power supply that comes with the unit. The Sharps Terminator can be used while left plugged into the power supply charger, or used remotely until the battery is discharged. The device is able to burn from 40 to over 200 needles per charge, depending on needle gauge and length burned. The unit (pictured below) is cylindrical in construction and approximately 4.5" in diameter and 7" in height.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

The Sharps Terminator® is a needle destruction device. It can be effective for destruction of sharps which fit into the approved range of syringe and needle sizes for which it is designed.

As an alternative to the use of a Sharps Terminator®, used needles and sharps can be disposed of in a conventional sharps container. In addition, needle and syringe sizes and types which are outside the working range of the Sharps Terminator® must also be disposed of in a conventional sharps container.

VII. MARKETING HISTORY

The Sharps Terminator® has not been marketed in the United States or any foreign country.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Below is a list of the potential adverse effects (e.g., complications) associated with the use of the device:

- There is always a risk of needle stick injury when handling sharps. Sharps may be disposed of with the Sharps Terminator® or in a Sharps container. Persons handling sharps should be trained in O.S.H.A. safety methods including blood-borne pathogens risk.
- The Sharps Terminator® works with electricity and generates heat. If the device is immersed and/or instructions are not followed, there is a risk of shock or burn.
- Contents of the Sharps Terminator® swarf tube must be considered potentially sharp and biohazardous. If instructions are not followed there is a risk of sharps injury and contamination. Regular decontamination of the device is recommended to ensure that the outer surfaces do not become contaminated.

IX. SUMMARY OF PRECLINICAL STUDIES

Product testing has been done to assess the following:

- Aerosol Biohazard Validation - Sharps Terminator® units were evaluated when used with syringe/needle combinations containing high concentrations of resistant indicator organisms. Results showed that risk of aerosol contamination resulting from the use of the machine is very low.
- Ozone Exposure – The Sharps Terminator® product was evaluated to ensure that ozone generated during use and activation of the UV lamp did not exceed regulatory standards. The device passed the test
- IEC 60601-1 Electrical safety – A full battery of electrical safety testing was done on the Sharps Terminator® and it meets all electrical safety requirements.
- Electromagnetic Compatibility (EMC) – The product was tested and meets EMC requirements.
- Cleaning Validation – Recommended cleaning methods were validated to be effective.
- Software Testing – Satisfactory software testing was done in accordance with the appropriate risk level for the Sharps Terminator®.
- Analysis of Swarf – Analysis performed on the swarf (needle remains) found after sharps destruction indicated that there may occasionally be sharp needle fragments and potential biohazard associated with the swarf contents. Device instructions are to dispose of the swarf contents in puncture resistant containers and handle swarf as a potential biohazard.

- Safety Testing – Testing was done to ensure that repeated use up to 200 consecutive times does not cause the device to overheat or otherwise create a safety hazard. The device passed this testing.

X. SUMMARY OF PRIMARY CLINICAL STUDY(IES)

The applicant performed a clinical study to establish a reasonable assurance of safety and effectiveness of Sharps Terminator to safely destroy 18-27 gauge needles up to 2 inches. This study was performed at six medical facilities in the US. Data from this clinical study were the basis for the PMA approval decision. A summary of the clinical study is presented below.

A. Study Design

Pivotal Clinical Study Design: The clinical study that formed the basis for the data analysis finding that the Sharps Terminator® is safe and effective for its intended use was a prospective, non-randomized, non-interventional, non-significant risk, open label, consecutive series study.

Major study design characteristics:

- The study was undertaken at 6 medical facilities which included 2 facility groups
  - 3 hospitals where the device was evaluated in the following areas: ER exam room, Lab, Medical/Surgical Unit, Patient Rooms, Medication Room, Labor & Delivery Room
  - 3 outpatient clinics/Medical Offices
- A total of 717 assorted combinations of needles from 18g 1" to 28g 0.5" and syringes from 3cc to 20cc's (Sharps) were kitted and subsequently destroyed
  - Each syringe was filled with a non-infectious or sterile inert solution prior to destruction
  - The study did not involve treatment of any type and no patients were involved
  - No humans or animals were injected with kitted Sharps.
- The study involved 19 different medical professionals who
  - routinely handled hypodermics in the course of their workday,
  - had training in Blood-borne pathogens
  - and were qualified by training or license to use/dispose of Sharps
  - each site enrolled a maximum of 12 subjects and at least one subject in each Facility type was left handed.
- The duration of the study was 2 months from the start of enrollment to the last subject, last visit.

The Statistical Methods:

Sample Size

The criteria established for determining whether the device was effective were: (1) A point estimate (PE) for proportion destroyed ≥ 95% and (2) a lower bound of the 95% confidence interval (LBCI) ≥ 93%. A simulation was conducted based using Clopper-Pearson 'exact' 95% confidence intervals. This simulation shows that a sample size of 720 will yield a PE ≥ 95% and an LBCI > 93% when 684 needle destruction events (or more) are deemed successful and 36 (or

fewer) needle destruction events are deemed to fail. Results for all indicated needle sizes were included and pooled; however, a greater number of needle sizes was included at the extremes of needle diameter and needle length to assure that device performance is robust within the domain of sizes it is designed to address. Accordingly, the sample size was apportioned accordingly (see Table 1):

Table 1 Needle Sizes and Numbers

Syringe Size	Needle Length	Needle Gauge	Total to be Destroyed
20	1	18	100
3	1.5	18	38
10	1.5	18	37
5	2	21	100
20	0.5	23	37
10	0.75	23	39
10	1	23	38
5	1	23	40
5	1.25	23	37
5	1.5	23	38
3	0.5	30	103
3	0.625	27	37
20	1.25	27	38
3	1.5	27	38
			720

Interim Analysis

No interim analysis was planned for the study. Complications, however, were monitored continuously to assure that unexpected adverse events or unexpected rates of complications known to be associated with sharps disposal were evaluated. No adverse events were reported in this study.

Data Analysis

The analysis plan outlined below includes descriptions of planned statistical tests. A summary of planned statistical tests is presented in Table 2. The score confidence with continuity correction was used to evaluate whether there is a difference in proportion between sizes where n = 100 when compared to the remainder of the entire sample of 720 with the subsample of 100 removed.

Table 2 Summary of Planned Statistical Tests

Test	Purpose	Expected Result

Clopper Pearson 'Exact' Confidence Interval, all results pooled N = 729	Overall test of effectiveness	PE ≥ 95% LBCI ≥ 93%
Score confidence interval with continuity correction Size Specific where n = 100; CI for difference between this proportion and remainder of the entire sample of 620	Tests of extreme diameters and lengths (3 tests)	Proportion difference includes zero (no difference, 99% confidence interval)
Clopper Pearson 'Exact' Confidence Interval, Size Specific where n = 35	Tests of individual needle configurations	PE > 85% in each instance
Confidence Interval of each complication type	Safety	No Differences

There was no external evaluation groups used in this study.

1. Clinical Inclusion and Exclusion Criteria

   1. Male & Female Health Care Workers (HCWs) 18 yrs to 75 yrs who routinely handle hypodermics in the course of their workday duties, have training in Blood-borne pathogens, and are qualified by license or training to use/dispose of hypodermic needles.
   2. Those workers who are unwilling to participate, unwilling to follow the protocol, are unwilling to sign a HIPAA form or who are known to be pregnant, a prisoner, mentally incompetent, and/or alcohol or drug abuser were excluded.

The Procedure Schedule for the trial was as follows:

- Screening/Consent/Enrollment
- Training
- Device Installation/Inventory/Location Form
- Completion of Demographic Data
- Assignment of Sharps Kit
- Sharps Destruction/ Completion of Sharps Destruction Log
- Photography of Location and destroyed Sharps
- Completion of User Satisfaction Questionnaire
- AE assessment
- Release from Study

All procedures were completed over the course of a single day at each center.

2. Follow-up Schedule

The Procedure Schedule for the trial was as follows:

- Screening/Consent/Enrollment
- Training
- Device Installation/Inventory/Location Form
- Completion of Demographic Data

- Assignment of Sharps Kit
- Sharps Destruction/ Completion of Sharps Destruction Log
- Photography of Location and destroyed Sharps
- Completion of User Satisfaction Questionnaire
- AE assessment
- Release from Study

All procedures were completed over the course of a single day at each center.

3. Clinical Endpoints

With regards to safety, the primary safety endpoint was met and no complication or adverse event rates were observed that appear to be associated with inferior performance of the investigational device as demonstrated by device related SAE's or UADE's.

With regards to effectiveness, The Primary efficacy endpoint was: Destruction of the needle body to a blunt "stub" of 1/16 inch or less in length (Rating 2 or 3 on a needle Destruction Scale) for 95% of all tested needles in no more than 2 attempts.

There were no secondary endpoints, but informational data on subject demographics as including occupation, type of certification, education, height, weight and handedness were collected. The location of the device, the height in relationship to the participant, and the power source for the device used was also collected for each location of the device and for each participant.

With regard to success/failure criteria, the success of the Sharps Terminator was based upon the following clinical criteria being met at the completion of the study:

1. Destruction of the needle body to a blunt "stub" of 1/16 inch or less in length (Rating 1 or 3 on the needle Destruction Scale) for 95% of all tested needles.
2. No complications or adverse event rates are observed that appear to be associated with inferior performance of the investigational device as demonstrated by device related SAE's or UADE's.

The Clinical Investigation was based on the FDA Guidance Document titled *"Premarket Approval Applications (PMA) for Sharps Needles Destruction Devices: Final Guidance for Industry and FDA March 2, 2001"*. A total of 720 needle/syringe combinations were evaluated using up to 3 Sharps Terminator Investigative devices per site at two Healthcare Facility Groups and six investigational centers in the United States. Sites were grouped by Facility type with 3 sites in each group (e.g. Hospitals, Outpatient Clinics/Medical Offices).

The number of Health Care Facility Groups (3 investigational centers per group) determined the number of syringe/needle combinations required for destruction. Two Facility groups of 3 investigational sites were enrolled, and each group was provided 360 kitted combinations or 120 needle/syringes per site.

B. Accountability of PMA Cohort

At the time of the database lock, 19 subjects enrolled in the PMA study, 100% (19/19) were available for analysis at the completion of the study. This cohort destroyed 717/720 Sharps and all data was available for evaluation.

C. Study Population Demographics and Baseline Parameters

A summary of the subject demographics of the study are as follows:

Table 3 Demographic Data Summary

Site Number	# of Subjects	Occupation							Education					Credential			Average Age	Gender		Avg. Hgt.	Avg. Wt.	Dominant Hand	
		LVN	Phlebotomist	RN	Pharm Tech	Med Tech	Para Medic	CRC	HS	AS	BS	TECH/ DIPOLMA	MS	License	Certified	Registered	Years	M	F	Inches	lbs	Left	Right
1	4	2	0	1	0	0	1	0	1	1	0	1	0	2	0	1	44	0	4	66	168	1	3
2	3	0	0	3	0	0	0	0	0	1	1	1	0	1	0	2	45	0	3	66	178	0	3
3	3	0	0	3	0	1	0	0	0	2	1	0	0	2	0	1	56	2	1	67.7	156	0	3
4	3	0	1	1	1	0	0	0	2	1	0	0	0	1	1	0	40	1	2	65	148	0	3
5	3	0	0	1	0	0	0	1	1	0	2	0	0	0	1	3	43	1	2	67	185	1	2
6	3	0	0	2	0	1	0	0	0	0	2	0	1	1	0	1	45	1	2	66	163	1	2

Race was not considered relevant to the use of the device and therefore that information was not collected.

D. Safety and Effectiveness Results

The ability of the Sharps Terminator Device to destroy hypodermic needles exceeded the target point estimate for successful destruction percent; and the lower bound target of the 95% confidence interval was higher than the target as well. Accordingly, findings of this study show that the device exceeded the success threshold on both measures. The difference in proportion of success for extreme sizes was compared to all other needle sizes using the Newcomb Hybrid Method with continuity correction (based upon score confidence intervals). Results are presented in Table 5. For each of the three extreme sizes (extreme by gauge or length), the confidence interval for the difference between proportions includes zero, indicating no evidence of difference from the remaining needles. (A 27 gauge needle was the smallest in the study whereas the original protocol stipulated a 30 gauge needle which became unavailable). These results are consistent with a priori hypotheses. The point estimate and exact 95% confidence intervals for destruction across all needle sizes are shown in Table 4. Exact confidence intervals by needle gauge and syringe size are shown in Table 6.

Table 4. Success and Failure of Sharps Destruction

Success (Count)	Failure (Count)	Target Point Estimate (%)	Actual Point Estimate (%)	Target Lower Bound (95%)	Obtained 95% CL (Upper/Lower Bound)

704	10	95%	98.4%	93%	97.27%/99.23%

Table 5 Confidence Intervals between Proportions Comparing Extreme Sizes to All Other Sizes

Needle Width (Gauge)	Needle Length (Inches)	Success	Failure	Success (All Other Sizes)	Failure (All Other Sizes)	95% Confidence Interval for the Difference[1]
18	1”	95	1	610	11	-4.78 to 2.50%
21	2”	98	2	608	9	-6.33 to 1.62%
27	0.5”	99	2	607	9	-6.25 to 1.63%

[1] Newcombe, R. Interval estimation for the difference between independent proportions: comparison of eleven methods. Statistics in medicine, 1998, 17, 873-890.

Table 6 Exact 95% Confidence Intervals by Size

Size	Success	Failure	Observed % Success	LBCI	UBCI
1"x18	95	1	98.96%	94.33%	99.97%
1.5"x18	78	0	100.00%	95.38%	100.00%
2"x21	98	2	98.00%	92.96%	99.76%
0.5"x23	37	1	97.37%	86.19%	99.93%
.75"x23	39	0	100.00%	90.97%	100.00%
1"x23	77	0	100.00%	95.32%	100.00%
1.25"x23	36	2	94.74%	82.25%	99.36%
1.5"x23	37	1	97.37%	86.19%	99.93%
.625"x25	37	0	100.00%	90.51%	100.00%
0.5"x27	99	2	98.02%	93.03%	99.76%
1.25"x27	35	2	94.59%	81.81%	99.34%
1.5"x27	38	0	100.00%	90.75%	100.00%

E. Financial Disclosure

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation. The pivotal clinical study included six clinical sites at five locations. None of the clinical investigators had disclosable financial interests/arrangements as defined in sections 54.2(a), (b), (c), and (f). The information provided does not raise any questions about the reliability of the data.

XI. SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

There was no supplemental clinical information in this study.

XII. PANEL MEETING RECOMMENDATION AND FDA’S POST-PANEL ACTION

Device did not go the Panel.

XIII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Effectiveness Conclusions

The Sharps Terminator®, performs well above the criteria established for success. The ten non-destruction events that occurred during the study did not subject the operator to danger and appeared to be related to the operator learning curve for the device. The ability of the device to destroy sharps and to remove this hazard from a health care environment safely was demonstrated across the range of needle sizes stipulated in the device indication for use. The Sharps Terminator® effectively destroyed sharps in the form of needles mounted on syringes with a very high level of efficiency. Studies showed that users became more proficient with use and experience a very high level of effectiveness in sharps destruction using the device.

B. Safety Conclusions

The risks of the device are based on handling sharps, whether using a conventional sharps container for disposal or if using the Sharps Terminator® and are also based on data collected in a clinical studies conducted to support PMA approval as described above. Safety studies demonstrated that the device can be operated effectively and safely by trained personnel in a wide range of needles, syringes, and medical settings. No adverse events were experienced in the testing of the device.

C. Benefit-Risk Conclusions

The probable benefits of the device are also based on data collected in a clinical studies conducted to support PMA approval as described above Use of the Sharps Terminator® allows health care institutions to minimize the overall use of sharps containers, thereby reducing the frequency of the need to replace and dispose of them. The waste stream for sharps containers remains hazardous and therefore disposal is significantly more expensive for health care institutions. Sharps containers are biohazards as well as sharps risks. Any minor added risks which may be associated with the use of the Sharps Terminator® are offset by the overall reduction of sharps container usage and disposal in a given institution.

In conclusion, given the available information above, the data support that the Sharps Terminator® to safely destroy 18-27 gauge needles up to 2 inches (approx. 5 cm) and the probable benefits outweigh the probable risks.

D. Overall Conclusions

The data in this application support the reasonable assurance of safety and effectiveness of this device when used in accordance with the indications for use.

The Sharps Terminator® performs well above the criteria established for success. The ten non-destruction events that occurred during the study did not subject the operator to danger and appeared to be related to the operator learning curve for the device. The ability of the device to destroy sharps and to remove this hazard from a health care environment safely was demonstrated across the range of needle sizes stipulated in the device indication for use.

XIV. CDRH DECISION

CDRH issued an approval order on February 17, 2016.

The applicant's manufacturing facilities have been inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820).

XV. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the device labeling.

Post-approval Requirements and Restrictions: See approval order.

XVI. REFERENCES

NA