

## Sharps Terminator Quick Reference Product Sheet

**FDA Number /** P120018  
**CE Number /** EN60601-1-2-2007  
**PMA Number /** P120018 Sharps Terminator  
**Patent Number /** 9,327,085 B2  
**FEI Number /** 3011328602



Quality Manual ISO 13485 § 4.2.2 & 21 CFR 820.20  
Competence, Awareness & Training ISO 13485 § 6.2.2 & 21 CFR 820.25  
Design and Development Review ISO 13485 § 7.3.4 & 21 CFR 820.30 (e) (ENG-SOP-0009-F1)

### Sharps Terminator Product Specifications (On box):

Needle Range 18G-31G  
Needle Length 1/2 in (12mm)-2in (50mm)  
Syringe Range 3cc-20cc  
Battery Pack 4.8V NiMH  
Battery Charger 7.5V 3000mA

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Sharps Terminator. This device is indicated for use by individuals and healthcare professionals to safely destroy 17-31 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. We are pleased to inform you that the PMA is approved.

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Submission Number: P120018/SOO1      Received: 5/25/2017 A  
Applicant: SHARPS TERMINATOR, LLC      Device: Sharps Terminator  
Pro-code: MT Estimated product 3-year life / 12K device cycles

Foreign company registrations number- upon request  
Domestic company registration number-upon request

Additional documentation is available upon request.