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AUG - 1 1996

4464 McGRATH STREET #114 • VENTURA, CA 93003 • (805) 658-7768

REVISION OF 510K SUMMARY
(as required by 807.92 (c))
May 20, 1996

K955514

Submitted by:

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November 27, 1995

Trade name - Sharps Safe 1.5
Sharps Safe 2.0

Common name - Sharps Container

Classification name - Sharps Container 80MMK 880.5570

Equivalent device being legally marketed:

Trade name - Sharps A Gator

Manufactured by: Devon Industries, Inc.

510K Approval Number: K943892

Description:

The device is comprised of a 1.5 inch diameter plastic tube (model 1.5), or a 2.0 diameter plastic tube (model 2.0). Securely attached to each end is a plastic cap. Secured inside the cap attached to the bottom end is a hard plastic disc designed to prevent needle penetration. The cap on the top end has a ¼ inch hole in the center. Radiating from the hole are slits cut in the plastic which form flaps through which a sharps can be inserted. A vinyl cover is provided for the top to provide a moisture tight seal.

Intended Use:

Sharps Safes are designed to be used by Paramedics or Home Care Providers who need a small, portable and rugged sharps container which can be used in remote locations to dispose of contaminated needles.

Technological Characteristics:

Predicate devices which we surveyed all had some shortcomings. They were either too large, too small, wouldn't contain the sharps if mishandled, blood could leak out, would shatter if struck, couldn't be attached to the outside of a drug box, or the contents couldn't be seen.

All of these failings were addressed when designing the Sharps Safe and eliminated.

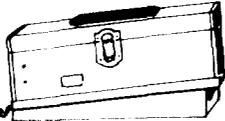
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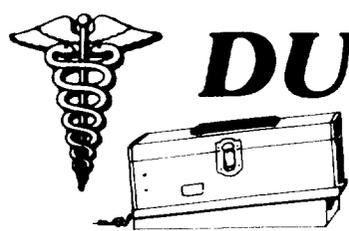
Non Clinical Tests:

The summary data derived from mechanical testing are as follows:

- 1) Impact Resistance: No needle ejection when dropped from eight (8) feet onto concrete. No damage to container.
- 2) Puncture Resistance:
 - 1.5 - 5.12 lb. average for sides.
 - 6.56 lb. average for bottom.
 - 2.0 - 5.80 lb average for sides.
 - 6.99 lb. average for bottom.
- 3) Wall Thickness:
 - 1.5 - .072 inches average for sides.
 - .1174 inches average for bottom.
 - 2.0 - .078 inches average for sides.
 - .1125 inches average for bottom.
- 4) Sharps Closure - Pull Test - 45 lb. for 24 hours.
- 5) Capacity:
 - 1.5 - 15.8 cu. in./6.75 oz.
 - 2.0 - 28.2 cu. in./12.30 oz.
- 6) Leakproof Test: The bottom is leakproof. The top is also leakproof when the vinyl cover is in place.
- 7) Disposal: Sharps Safes contain no heavy metals and can be incinerated.
- 8) Attachment Strap Test: A Sharps Safe will support 45 pounds when secured to a surface by the attachment straps.

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Clinical Tests:

Not required.

Conclusions:

It is very clear that there is a real need for a sharps container that is designed specifically for Paramedics and Home Health Care Professionals.

All of the existing devices on the market have shortcomings which make them unsuitable for Paramedic use. Sharps Safes were designed to fill this void.

The nonclinical tests provided us with the design and materials to be used, and the clinical tests refined the parameters of the materials. These tests also revealed that a better system was needed to secure the container to the drug box. It also became apparent that two sizes would be beneficial (2 inch and 1.5 inch).

The combined talents of sixty (60) fire department Paramedics were used to develop Sharps Safes.

We feel that they meet the need.