

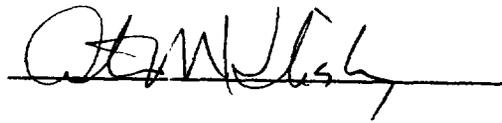
MedScience™

K 960641

510K Summary

MAY 17 1996

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A handwritten signature in black ink, appearing to read "Autumn Kliskey", is written over a horizontal line.

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Trade Name – Recap-1
Common Name – Needle Recapping Device
Classification Name – Hypodermic Single Lumen Needle (Accessory)

Substantial Equivalent: Needlesafe I
Manufactured by Ingenious Technologies Corp.
510K # K936235

Description of Recap-1

Recap-1 is 3"x4"x4.5" made of red pigmented ABS plastic weighing 6.5 ounces. The faceplate has 5 precise apertures to accommodate a majority of needles and their corresponding caps that are in the healthcare market today. It is labeled Recap-1, one-handed needle recapper. The five apertures identify by name the different types of needles that can be resheathed. Below the apertures it is stated "Do Not Use 2 Hands" thus conforming with OSHA guidelines and 29 CFR Part 1910.1030.

Intended Use of Recap-1

Recap-1 is used following OSHA guidelines to safely recap conventional needles prior to transport to an authorized sharps container in order to minimize the possibility of accidental needlesticks from occurring, after the injection procedure has been completed.

The device would be used in all healthcare environments to protect healthcare workers and patients from needlesticks after the injection process has taken place.

Remove the cap from the sterile needle by pulling back with a straight motion to avoid needle point damage. The needle cap is then placed in the appropriate aperture on the faceplate. After the injection procedure, the needle is placed into the cap with *one hand only*. Push down until you feel or hear the cap lock into place. The entire recapped needle is then removed from Recap-1 *with one hand* and transported safely to an authorized sharps container for disposal.

Technological Characteristic Comparison Between Recap-1 and Needlesafe II

Three basic technological differences are noted between Recap-1 and Needlesafe II.

1. Recap-1 is larger than Needlesafe II.
2. Recap-1 has 5 apertures. Needlesafe II has only one aperture. Recap-1 allows for various sized needles and corresponding caps to be used.
3. Recap-1 has non-skid EDPM rubber extruded “feet” for stability. Needlesafe II has an independent base for possible adherence to a surface.

The difference in the technological characteristics noted above do not affect the safety and effectiveness of Recap-1 with regards to Substantial Equivalence.

Non-clinical testing of both devices actually presented an easier recapping procedure with Recap-1. In testing, removing the caps and placing them in Needlesafe II, it became apparent the caps could stick due to the single size aperture. Recap-1 had no sticking or failures whatsoever. This is attributed to the fact that Recap-1 has 5 different apertures allowing for a larger variety of cap sizes to be used, as well as possessing clear, unrestricted openings where the caps rest.

BENCH TESTING OF RECAP-1

Bench Testing was performed evaluating 10 needles of each cap size as defined in the enclosed Needle Cap Fit Guide. Tests included (1) if the cap was sticking in the device during the one handed needle recapping procedure and (2) if there was a problem removing the recapped needle from the device.

| Cap Size | Cap Sticking in Device | Problem Removing Recapped Needle |
|--|-----------------------------------|---|
| Terumo B-D 1/4" Round | None | None |
| B-D 1/4" Round | None | None |
| Novalon 7/16" Hexagon 16, 18, 20, 22 Gauge | None | None |
| Monoject 7/32" Square 250 E Series | None | None |
| Monoject 5/16" Square 250, 200, 205, 220 Series | None | None |
| Accuderm 9/32" Square | None | None |
| B-D 9/32" Square | None | None |
| MPL 9/32" Square | None | None |

The above test results demonstrate no problems or failures were encountered when recapping the needles or removing the recapped needle from the Recap-1 Device.

Needle Resheather

Allow single handed needle cap and recatheterization.

- Securely grips needle caps, phlebotomy and intravenous catheter caps.
- Complies fully with the newest OSHA standards.
- Can be mounted wherever syringes are used. Base can be adhered to any clean smooth surface.
- Reusable - The top portion of the unit can be removed from the base and steam autoclaved, gas sterilized, or disinfected by wiping with or soaking in alcohol.
- Can also be used as a syringe holder.
- Unit measures 2 1/2"W x 3"H.

NeedleSafe II™ is a trademark of Ingenious Technologies Corporation.

Needle Resheather & Needle Cap & Blood Tube Holder

| HCL No. | Description | Price Each |
|---------|--------------------------------------|------------|
| A 7375 | Needle Resheather | \$14.50 |
| B 7377 | Needle Cap Holder | 32.60 |
| C 7379 | Blood Tube Holder | 32.60 |
| D 7373 | Needle Cap & Blood Tube Holder Stand | 10.30 |

The Needle Cap & Blood