

K 963830

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510(k) Summary

K963830

Company: Imagination Medical Inc.
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Contact: Mr. Gary Burdette

Device Name: SC001 Sharps Container

Common Name: Sharps Container

Classification Name: 21 CFR 880. Type II

Date of Summary Submission: December 9, 1996

Predicate Devices:

The SC001 is compared to the below mentioned containers in that it conforms to the same standards as its predicates. This container is made from aluminum with a water tight screw on lid. The material is puncture resistant. The predicate devices are made of pre molded plastic compared to our product which is made of 6061 aluminum. Both comparison models have tight fitting plastic lids and are disposal. Our product has a aluminum screw on lid which is tight fitting and prevents leakage of the contents.

1. B.D. Home Sharps Container K943575
2. Sage Sharps Disposal System K943660

Testing:

6061 aluminum has a shear rate of 20000 PSI with a wall thickness of .007 and a base of .02, it would take 3 lbs of direct pressure for a needle to penetrate this container. Test were designed to demonstrate when a 1cc Insulin syringe with a .5 inch needle of .014 OD thickness collapse. It was found that in every situation that the needle bent when .632 ounces and broke at .7 oz of direct pressure was applied. At this amount of pressure it was determined that the needle would not penetrate the container. Needles are also placed in the container in an upright posture placing the sharp at the bottom of the container.

A shake test at 10 revolutions showed that the needles were completely bent but, allowed no penetration through the sides or the bottom of the container.

In conclusion it is felt that our product meets and exceeds the standards adopted by FDA and is substantially equivalent to other legally marketed sharps containers.

Description of Device:

A one piece aluminum container designed for the safe and easy disposal of contaminated needles and syringes. Container is designed of thin walled puncture resistant 6061 aluminum with a screw on leak proof lid. Container is designed to hold up to two (2) 1cc syringes and is completely disposable in accordance with local and state regulations.

Intent for Use:

This container is for use by Law Enforcement Agencies. Law Enforcement Officials who frequently encounter syringes and other sharps during searches of suspects, vehicles, property or location.