

OCT 11 1996

K962149

**Safety and Effectiveness Summary**

for 510(k) Premarket Notification K962149 for Safety Cradle® sharps container

**The manufacturer  
of record is:**

Specialized Health Products Incorporated  
655 E. Medical Drive  
Bountiful, Utah 84010

**Intended Use:**

For storage and disposal of used sharps devices.

**Classification Number:**

80MMK

**Classification Name:**

Sharps Container

**Regulation Number:  
Class:**

880.5570  
Class II

**Common/Usual Name:**

Sharps Container

**Commercial Name:**

Safety Cradle®

**Performance Standards:**

None established under section 514.

**Substantial Equivalence:**

The Safety Cradle sharps container is substantially  
Equivalent in function to:

Specialized Health Products Incorporated  
655 E. Medical Drive  
Bountiful, Utah  
Sharp-Safe Sharps disposal Box K901321 (5/11/90)

In developing the information for this submission, the CDRH draft Guidance on the  
Content and Format of Premarket Notification [510(k)] Submissions for Sharps  
Containers was referenced.

## DEVICE DESCRIPTION

The device is a molded plastic container with various features designed to allow the admission of used sharps while preventing the user from coming in contact with the contents of the container. It has provisions for both temporary and permanent closure of the container. When closed permanently, the container is disposed of in accordance with medical waste procedures.

The Safety Cradle sharps container utilizes a unique two part design that provides the following features:

1. Unique automatic closure means for the disposal of sharps utilizing a biased flap referred to as the Safety Cradle, a living hinge and a depressable cover that is linked to the biased flap and living hinge.
2. A secondary temporary closure with temporary lock and a handle for safe transport. In between uses, the biased flap and cover provide two barriers of protection against exposure to sharps within the container.
3. Permanent closure when container is full.
4. Highly absorbent pad with gelling compound for fluid control.
5. Left handed and right handed phlebotomy needle extractors.
6. Multiple uses in applications that include a wall mounted container, table mount use and as a free standing container.
7. Safety Cradle feature provides a unique means for a horizontal drop of a sharp.

**PRODUCT COMPARISON**  
**Safety Cradle vs. Sharp Safe**

<u>FEATURE</u>	Predicate Device Sharp Safe	Proposed Device Safety Cradle®
510(k) Clearance	K901321	K962149
Puncture resistance meets ASTM standards	yes	yes
Horizontal drop of sharps	yes	yes
Stable in free standing position	yes	yes
Leak proof in upright position	yes	yes
Potential for fingers to accidentally slip into container	yes	no
Injection molded parts	no	yes
Fill indicator line	no	yes
Instructions on container	no	yes
Phlebotomy needle extractor(s)	no	yes
Nestable	no	yes
Sufficient clarity to view fill level (Meets ECRI standards)	no	yes
Closure Mechanisms: Automatic closure between disposal of sharps	yes	yes
Permanent closure when container is full	with tape	yes
Handle	no	yes
Absorbent pad to resist leakage in positions other than upright	yes	yes