

K964387



Graphic Controls  
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510(K) Summary

**510(K) SUMMARY  
POINT OF USE II SHARPS-A-GATOR<sup>®</sup>**

**Date:** October 20, 1996

**Manufacturer:** Graphic Controls, Devon Products  
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Chatsworth, CA 91311  
Registration # 2020423

Graphic Controls, Devon Products  
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**Device Trade Name:** Point of Use II Sharps-A-Gator<sup>™</sup>

**Common Name:** Sharps Collection/Disposal System

**Classification Name:** Accessory to Hypodermic Needle, Class II

**Regulatory Reference:** 80FMI

**Predicate Device:** Point of Use Sharps-A-Gator<sup>®</sup>  
Sage In-Room and Sharpstar Disposal System

**Description:**

- Devon's Point of Use II Sharps-A-Gator<sup>®</sup> will be used as a single use only container for sharps collection/disposal.
- The Point of Use II Sharps-A-Gator<sup>®</sup> comes in 2.3 +/- .5 gallon and 2.8 +/- .5 gallon containers. Both container buckets are available in clear, translucent and opaque color versions.
- The top housing assembly and base are made of polypropylene plastic material and processed through injection molding.
- The top cover includes the top cover housing, moving tortuous path with an actuator, a flapper and a lid. These components are assembled during the manufacturing process. The base is joined with the top cover assembly by the end user.
- The assembled container can be secured to a locking bracket or into a cabinet, or used as a free standing unit.
- The Point of Use II Sharps-A-Gator<sup>®</sup> has a horizontal top load opening and a moving tortuous path with an actuator that enable the user to "flush" sharps that lodge in the tortuous path without reaching into the container.
- The Point of Use II Sharps-A-Gator<sup>®</sup> moving tortuous path restricts hand entry.
- The Point of Use II Sharps-A-Gator<sup>®</sup> is made with heavy metal free materials that are safe to incinerate and autoclave.

**Intended Use:**

- The intended use of this device is to contain used sharps in a puncture resistant container in order to aid the reduction of accidental needlestick injuries.
- The Point of Use II Sharps-A-Gator<sup>®</sup> can be used in any area requiring discarding prior of sharps prior to their final disposal. e.g. operating room, doctor's office, pediatrics, patient's room, etc.

**Physical/Technical Comparison:**

**SIMILARITIES:**

Point of Use II Sharps-A Gator<sup>®</sup> (New Device) and Point of Use Sharps-a-Gator<sup>®</sup> (Predicate Device)

- have the same intended use
- are manufactured through injection molding

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- are made with the same polypropylene materials that contain no heavy metals and are safe to incinerate and autoclave
- are both designed with comparable wall thickness
- are both puncture resistant per ASTM's draft # 17 requirements
- are both labeled in accordance with OSHA requirements
- both feature one hand, one step sharps disposing
- both feature a tortuous path that impedes hand entry
- both may be used as either wall mounted or floor standing models
- both have a clear top with clear or opaque base containers

Point of Use II Sharps-A-Gator<sup>®</sup> (New Device) and Sage In-Room and Sharpstar sharps disposal system (Predicate Device)

- have the same intended use
- feature horizontal loading disposal
- both feature a moving tortuous path that restricts hand entry
- both feature an override system that enables the user to flush sharps into the container sharps that may lodge in the tortuous path
- both have the same intended use
- both have clear top assemblies

#### DIFFERENCES

Point of Use II Sharps-A-Gator<sup>®</sup> (New Device) and Point of Use Sharps-A-Gator<sup>®</sup> (Predicate Device)

- The new device features a moving tortuous path with an actuator that enables the user to flush sharps that may lodge in the tortuous path
- The moving tortuous path and flapper of the new device closes the top opening when sharps are dropped into container
- The new device features no needle unwinder. The predicate device features a manual needle unwinder

The Point of Use II Sharps-A-Gator<sup>®</sup> (New Device) and Sage In-Room and Sharpstar sharps disposal system (Predicate Device)

- The new device features horizontal top loading disposal while the predicate device features horizontal front loading disposal

#### Performance Summary

The following tests assure safety and effectiveness of Graphic Controls, Devon Products Point of Use II Sharps-A-Gator<sup>®</sup>

- Puncture Resistance test following ASTM Draft # 17
- Functional Drop test based on ECRI's guidelines

- **Leak Resistance and Stability based on OSHA 1910.1030 Blood Pathogens Standards requirement**
- **In-house assembly and wall thickness verification tests during manufacturing**
- **Functional tests during manufacturing**
- **Qualifying tests for moving tortuous path**

Point of Use II Sharps-A-Gator™ complies with all acceptance criteria listed above.

510(K) Number(if known):   K964327  

Device Name: Point of Use II Sharps-A-Gator®

Indication For Use:

The Point of Use II Sharps-A-Gator® will be used as a sharps container/disposal system. It can be used in any area requiring sharps collection prior to their final disposal. e.g. operating room, emergency room, patient room, pediatrics, doctor's office etc

The Point Of Use II Sharps A-Gator® is for single use only and must be disposed of after its maximum capacity level is reached.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_ Concurrence of CDRH, Office of Device Evaluation (ODE) \_\_\_\_\_

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The Counter Use \_\_\_\_\_

*(Handwritten initials)*