

K964519

EXHIBIT #12

510(k) Summary

DEC 20 1996

Kendall Curity® Thoracentesis Tray

In accordance with section 513(i) of the SMDA and as defined in 21 CFR Part 807.3 final rule dated December 14, 1994, this summary is submitted by:

Kendall Healthcare Products Company
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Date: November 7, 1996

1. Contact Person

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2. Name of Medical Device

Classification Name: Vacuum-Powered Body Fluid Suction
Apparatus
Common or Usual Name: Thoracentesis Tray
Proprietary Name: Curity Thoracentesis Tray

3. Identification of Legally Marketed Device

The proposed Kendall Curity Thoracentesis Tray is substantially equivalent in intended use, function and composition to the commercially available Kendall Curity Thoracentesis Tray, 510(k) No. K903569; Arrow International Pleura-Seal™ Thoracentesis Kit, 510(k) No. K870572; and Sherwood Medical Argyle® Turkel™ Safety Thoracentesis Procedure Tray, 510(k) No. K930847.

4. Device Description

The proposed Kendall Curity Thoracentesis Tray is a sterile, single use procedural tray containing the components required to perform a thoracentesis. This submission covers proposed changes to the aspirating needle and thoracentesis catheter. An ergonomically designed polycarbonate hub will be insert molded onto the needle cannula and a polyurethane hub insert molded onto the catheter shaft. In addition, the catheter shaft material will change from Teflon® to polyurethane. There

Exhibit 12 (continued)

will be no changes to the current dimensions or performance specifications.

In addition, a new product code will incorporate Kendall's thoracentesis catheter-over-needle with an automatic valve that acts to occlude the proximal end of the catheter lumen. The valve is an integral part of the catheter. Once the needle is withdrawn from the valve, a spring mechanism occludes the catheter lumen.

5. Device Intended Use

The Kendall Curity Thoracentesis Tray is intended to be used to drain fluid from the pleural cavity.

6. Product Comparison

The Kendall Curity Thoracentesis Tray is equivalent to the referenced predicate devices in that they are fabricated from similar materials have the same function and equivalent indications for use.

7. Nonclinical Testing

Biocompatibility testing was performed on the needle hub, catheter and automatic valve following ISO-10993 Biological Evaluation of Medical Devices. This testing found the material contained no toxic diffusible substances.

Functional/Mechanical testing was performed to determine hub pull-off force, potential for leakage, and siphoning capability of the automatic valve.