

## ATTACHMENT 1

### EVALUATION OF INFECTION RISK /FLOWCHART 1

#### **High Risk SUD: Endoscopic Vessel Harvesting Devices (878.4400 GEI)**

**Question 1:** Are endoscopic vessel harvesting devices non-critical devices?

The answer to Question 1 is “No” because endoscopic vessel harvesting devices make contact with a normally sterile area and have been designated by FDA to be critical devices.

Go to Question 2.

**Question 2:** Does FDA have postmarket data that suggest using a reprocessed endoscopic vessel harvesting devices may present an increased risk of infection?

At this time, the Company does not know of any postmarket data that suggest using a reprocessed endoscopic vessel harvesting device may present an increased risk of infection when compared to the use of an endoscopic vessel harvesting devices that has not been reprocessed.

The answer to Question 2 is “No.”

Go to Question 3.

**Question 3:** Do endoscopic vessel harvesting devices have features that may impede cleaning and disinfection or sterilization?

Endoscopic vessel harvesting devices have features that could impede thorough cleaning and adequate sterilization. In particular, endoscopic vessel harvesting devices incorporate components that have long narrow lumens, retracting parts, cautery surfaces, and small crevasses that are likely to trap blood and body tissue during normal use and that are not easily accessed and removed during cleaning. For example, endoscopic vessel harvesting devices have components that can be extended and retracted through long narrow lumens. During normal use, blood and body tissue is drawn into these narrow lumens. Likewise, to wash the scope during use,

saline is flushed into the site through one port, and is removed through a vacuum port. During normal use, blood and body tissue is drawn into this port. Additionally, during use the cautery surfaces develop a layer of electrified blood and body tissue which is very difficult to remove. Finally, the device consists of interchangeable subassemblies which have many small crevasses and narrow winding cavities. During use, these crevasses and cavities may harbor blood and body tissue after use that are not easily accessed or removed during cleaning. Because these components of endoscopic vessel harvesting devices are difficult to clean, terminal processing to sterilize such devices may not be successful and such reprocessed devices present a potential high risk of infection.

The answer to Question 3 is "Yes."

Go to Question 4.

**Question 4:** Does a reusable device exist that has an equivalent design and the same intended use?

At this time the Company does not know of any reusable endoscopic vessel harvesting devices with an equivalent design and same intended use as endoscopic vessel harvesting devices manufactured by the Company.

The answer to Question 4 is "No."

Go to Question 5.

**Question 5:** Are there recognized standards that may be used to determine if the SUD has been adequately cleaned and sterilized?

At this time there are no recognized consensus performance standards, tests recommended by the manufacturer, or CDRH guidance documents that may be used to determine if an endoscopic vessel harvesting device has been adequately cleaned and sterilized for reuse.

The answer to Question 5 is "No."

Go to Question 6.

**Question 6:** Is this a semi-critical device?

The answer to Question 6 is “No.” Endoscopic vessel harvesting devices are critical devices.

Therefore, endoscopic vessel harvesting devices pose a high risk of infection if reprocessed and reused.