

Device Schedule: Class III and Class IIb devices

| Class IIb | Intended purpose |
|--------------------------------------|--|
| Sterile polyurethane dressing | Intended to act as a primary or secondary layer in wound dressings, to serve as a barrier between the skin and/or wound and the environment, and to absorb exudate. |
| Sterile nasogastric intestinal tubes | Intended for use in an established gastrostomy tract as a replacement tube for the administration of nutrition, fluids, and medications to the stomach of a patient that is physically unable to manage nutritional intake through normal mastication and deglutition. |
| Sterile alginate dressing | Intended for use to absorb exudates and protect the wound from contamination. |

Device Schedule: Class IIa, Custom-made and other devices

| Device(s) | Risk Classification |
|---|---------------------|
| Enteral feeding pump | Class IIa |
| Sterile and non-sterile enteral feeding pump tubing sets | Class IIa |
| Sterile and non-sterile gastrointestinal feeding/aspiration tubes | Class IIa |
| Sterile and non-sterile cannulas and tips for aspiration and irrigation | Class IIa |
| Sterile powder free surgical gloves | Class IIa |
| Sterile Hypodermic syringe needles, with safety systems | Class IIa |
| Sterile Surgical Drainage Systems | Class IIa |
| Pneumatic compression equipment | Class IIa |
| Digital thermometers | Class IIa |