

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