



**Product Name: XTRK CATHETER REMOVAL TOOL**

**Product Description: XTRK CUFFED CATHETER REMOVAL DEVICE**

**US Product Classification: Class 1**

**Registration Number: 3015042203**

Part Number	Description	Classification	Regulation	Product Code	Product Code Description
I017-1165	XTRK Catheter Removal Tool	1	878.4800	GDJ	Clamp, Surgical, General & Plastic Surgery

21 CFR 878.4800 states the following:

*A manual surgical instrument for general use is a nonpowered, hand-held, or hand-manipulated device, either reusable or disposable, intended to be used in various general surgical procedures. The device includes the applicator, clip applier, biopsy brush, manual dermabrasion brush, scrub brush, cannula, ligature carrier, chisel, **clamp**, contractor, curette, cutter, dissector, elevator, skin graft expander, file, forceps, gouge, instrument guide, needle guide, hammer, **hemostat**, amputation hook, ligature passing and knot-tying instrument, knife, blood lancet, mallet, disposable or reusable aspiration and injection needle, disposable or reusable suturing needle, osteotome, pliers, rasp, retainer, retractor, saw, scalpel blade, scalpel handle, one-piece scalpel, snare, spatula, stapler, disposable or reusable stripper, stylet, suturing apparatus for the stomach and intestine, measuring tape, and calipers.*

These devices are considered Class I and are exempt from the premarket notification procedure.

*Macy Pyle*

Regulatory Affairs Management  
Macy Pyle

10/5/2020

Date

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