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Regulatory Classification for CareDry® System

The CareDry® System, comprising of a foam sponge and vacuum regulator, is 510k exempt. The foam sponge falls under product code NZU (Collector, Urine, Powered, Non-Indwelling Catheter) and Regulation number 21CFR876.5250 (urine collector and accessories). Per the regulation, urine collectors and accessories not intended to be connected to an indwelling catheter are 510k exempt.

The CareDry® System regulator falls under FDA product code KDP (Regulator, Vacuum) and regulation 21CFR880.6740 (Vacuum-powered body fluid suction apparatus). Per the regulation, vacuum regulators are 510k exempt.

TITLE 21 –FOOD AND DRUGS
CHAPTER I—FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H—MEDICAL DEVICES

PART 876 – GASTROENTEROLOGY-UROLOGY DEVICES
Subpart F – Therapeutic Devices

Sec. 876.5250 Urine collector and accessories

(a) *Identification*. A urine collector and accessories is a device intended to collection urine. The device and accessories consist of tubing, a suitable receptacle, connectors, mechanical supports, and may include a means to prevent the backflow of urine or ascent of infection.
(2) A urine collector and accessories not intended to be connected to an indwelling catheter, which includes the corrugated rubber sheath, pediatric urine collector, leg bag for external use, urosheath type incontinence device, and the paste-on device for incontinence.
(b) Classification – (1) Class II (special controls) for a urine collector and accessories intended to be connected to an indwelling catheter. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to 876.9.
(2) Class I (general controls). For a urine collector and accessories not intended to be connected to an indwelling catheter, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in 876.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of 820.180, with respect to general requirements concerning records, and 820.198, with respect to complaint files.
[48 FR 53023, Nov. 23, 1983, as amended at 63 FR 59228, Nov. 3, 1998; 65 FR 2317, Jan. 14, 2000; 66 FR 38802, July 25, 2001; 73 FR 34860, June 19, 2008]

PART 880 – GENERAL HOSPITAL AND PERSONAL USE DEVICES
Subpart G—General Hospital and Personal Use Miscellaneous Devices

Sec. 880.6740 Vacuum-powered body fluid suction apparatus

(a) *Identification*. A vacuum-powered body fluid suction apparatus is a device used to aspirate, remove or sample body fluids. The device is powered by an external source of vacuum. This generic type of device includes vacuum regulators, vacuum collection bottles, suction catheters and tips, connecting flexible aspirating tubes, rigid suction tips, specimen traps, noninvasive tubing, and suction regulators (with gauge).
(b) Classification. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to 880.9.
[45 FR 69682, Oct. 21, 1980, as amended at 63 FR 59229, Nov. 3, 1998]