



Product Name: SPECIMEN BASKET
Classification Name: TRAP, STERILE SPECIMEN
Product Code: BYZ
Device Class: 2
Regulation Number: 880.6740
Medical Specialty: General Hospital
Registered Establishment Name: TOBRA MEDICAL, INC.
Registered Establishment Number: 3013398027
Owner/Operator: Tobra Medical
Owner/Operator Number: 10053159
Establishment Operations: Specification Developer; Complaint File Establishment

[Code of Federal Regulations]
[Title 21, Volume 8]
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TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

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]