[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2016]
[CITE: 21CFR880.6740]

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.

Note: Class II devices the Food and Drug Administration (FDA) has also published a list of Class II (special controls) devices subject to certain limitations, that are now exempt from the premarket notification requirements under the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). FDA believes that these exemptions will relieve manufacturers from the need to submit premarket notification submissions for these devices and will enable FDA to redirect the resources that would be spent on reviewing such submissions to more significant public health issues. FDA is taking this action in order to meet a requirement of the Modernization Act.

U.S. FOOD & DRUG ADMINISTRATION

FDA Medical Devices Databases

Establishment:
DECHOKER LLC
4456 Raceway Drive
Concord , NC 28027
Registration Number: 3011422544
FEI Number*: 3011422544
Status: Active
Date Of Registration Status: 2017

Owner/Operator:
Dechoker, LLC
10433 Garda Drive
Trinity, FL 34655
Owner/Operator Number: 10048624

Establishment Name	Registration Number	Current Registration Yr
DECHOKER LLC NC/USA	3011422544	2017
• Catheters, Suction, Tracheobronchial		Specification Developer
• Apparatus, Suction, Operating-Room, Wall Vacuum Powered - Dechoker Model-2DCH01; Dechoker Model-2DCH02		Specification Developer; Complaint File Establishment

U.S. FOOD & DRUG ADMINISTRATION

Proprietary Name:	Dechoker Model-2DCH01; Dechoker Model-2DCH02
Classification Name:	APPARATUS, SUCTION, OPERATING-ROOM, WALL VACUUM POWERED
Product Code:	GCX
Device Class:	2
Regulation Number:	880.6740
Medical Specialty:	General Hospital
Registered Establishment Name:	DECHOKER LLC
Registered Establishment Number:	3011422544
Owner/Operator:	Dechoker, LLC
Owner/Operator Number:	10048624
Establishment Operations:	Specification Developer; Complaint File Establishment

U.S. FOOD & DRUG ADMINISTRATION

Device	Apparatus, Suction, Operating-Room, Wall Vacuum Powered
Regulation Description	Vacuum-powered body fluid suction apparatus.
Regulation Medical Specialty	General Hospital
Review Panel	General Hospital
Product Code	GCX
Premarket Review	Office of Device Evaluation (ODE: Division of Anesthesiology, Infection Control Dental Devices (DAGRID), General Hospital Devices Branch (GHDB)
Submission Type	510(K) Exempt
Regulation Number	880.6740
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible