



BioDerm, Inc. FDA Establishment Registration & Device Listing 2020

Establishment: BIODERM, INC.
12320 73rd Court North
Largo, FL 33773

Registration Number: 1063299

FEI Number*: 3001949129

Status: Active

Initial Distributor/Importer: Yes

Date Of Registration Status: 2020

Owner/Operator: BIODERM, INC.
12320 73rd Court North
Largo, FL 33773

Owner/Operator Number: 9032576

*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.

Proprietary Name: **CathGrip Double Strap; CathGrip Double Strap with Wing Seal; CathGrip Oval; CathGrip PEG Protect; CathGrip Single Strap; CathGrip Single Strap with Wing Seal; Fortitude; Tube Securement Device; Low Profile CathGrip Single Strap; Low Profile CathGrip Double Strap**

Classification Name: DEVICE, INTRAVASCULAR CATHETER SECUREMENT

Product Code: KMK

Device Class: 1

Regulation Number: 880.5210

Medical Specialty: General Hospital

Registered Establishment Name: BIODERM, INC.

Registered Establishment Number: 1063299

Owner/Operator: BIODERM, INC.

Owner/Operator Number: 9032576

Establishment Operations: Contract Manufacturer; Manufacturer



Proprietary Name:

Classification Name:	BioDerm Urine Collection Bag 1,000 mL Sterile Fluid Pathway
Product Code:	BAG, URINE COLLECTION, LEG, FOR EXTERNAL USE, STERILE FAQ
Device Class:	1
Regulation Number:	876.5250
Medical Specialty:	Gastroenterology
Registered Establishment Name:	BIODERM, INC.
Registered Establishment Number:	1063299
Owner/Operator:	BIODERM, INC.
Owner/Operator Number:	9032576
Establishment Operations:	Specification Developer

Proprietary Name:

Classification Name:	FreeDerm Adhesive Remover
Product Code:	SOLVENT, ADHESIVE TAPE KOX
Device Class:	1
Regulation Number:	878.4730
Medical Specialty:	General & Plastic Surgery
Registered Establishment Name:	BIODERM, INC.
Registered Establishment Number:	1063299
Owner/Operator:	BIODERM, INC.
Owner/Operator Number:	9032576
Establishment Operations:	Specification Developer

Proprietary Name:

	Faceplate Seals; Men's Liberty Acute with CathGrip; Men's Liberty Acute with CathGrip and Towel; Men's Liberty Acute without CathGrip; Men's Liberty; Men's Liberty Acute; BioDerm
Classification Name:	DEVICE, PASTE-ON FOR INCONTINENCE, NON-STERILE
Product Code:	NOA
Device Class:	1
Regulation Number:	876.5250
Medical Specialty:	Gastroenterology
Registered Establishment Name:	BIODERM, INC.
Registered Establishment Number:	1063299
Owner/Operator:	BIODERM, INC.
Owner/Operator Number:	9032576
Establishment Operations:	Contract Manufacturer; Manufacturer



Proprietary Name:

Classification Name:	BioDerm Penis Clamp; KindKlamp CLAMP, PENILE
Product Code:	FHA
Device Class:	1
Regulation Number:	876.5160
Medical Specialty:	Gastroenterology
Registered Establishment Name:	BIODERM, INC.
Registered Establishment Number:	1063299
Owner/Operator:	BIODERM, INC.
Owner/Operator Number:	9032576
Establishment Operations:	Manufacturer

Proprietary Name:

Classification Name:	BioPlus Skin Wipe TAPE AND BANDAGE, ADHESIVE
Product Code:	KGX
Device Class:	1
Regulation Number:	880.5240
Medical Specialty:	General Hospital
Registered Establishment Name:	BIODERM, INC.
Registered Establishment Number:	1063299
Owner/Operator:	BIODERM, INC.
Owner/Operator Number:	9032576
Establishment Operations:	Specification Developer

Proprietary Name:

Classification Name:	Faceplate Strip BANDAGE, ELASTIC
Product Code:	FQM
Device Class:	1
Regulation Number:	880.5075
Medical Specialty:	General Hospital
Registered Establishment Name:	BIODERM, INC.
Registered Establishment Number:	1063299
Owner/Operator:	BIODERM, INC.
Owner/Operator Number:	9032576
Establishment Operations:	Manufacturer