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 *Note Firm May Have Additional Establishment Types. Please Review Listings For Further Information.
Date Of Registration Status:	2020
Owner/Operator:	BIODERM, INC. 12320 73rd Court North Largo, FL 33773
Owner/Operator Number:	9032576

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**
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:	**BioDerm Urine Collection Bag 1,000 mL Sterile Fluid Pathway**
Classification Name:	BAG, URINE COLLECTION, LEG, FOR EXTERNAL USE, STERILE
Product Code:	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:	**FreeDerm Adhesive Remover**
Classification Name:	SOLVENT, ADHESIVE TAPE
Product Code:	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:	**BioDerm Penis Clamp; KindKlamp**
Classification Name:	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:	**BioPlus Skin Wipe**
Classification Name:	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:	**Faceplate Strip**
Classification Name:	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