



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:

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

Proprietary Name:

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

Proprietary Name:

Classification 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**
Product Code: DEVICE, PASTE-ON FOR INCONTINENCE, NON-STERILE
Device Class: NOA
Regulation Number: 1
Medical Specialty: 876.5250
Registered Establishment Name: Gastroenterology
Registered Establishment Number: BIODERM, INC.
Owner/Operator: 1063299
Owner/Operator Number: BIODERM, INC.
Establishment Operations: 9032576
Contract Manufacturer; Manufacturer



Proprietary Name:

Classification Name:

Product Code:

Device Class:

Regulation Number:

Medical Specialty:

Registered Establishment Name:

Registered Establishment Number:

Owner/Operator:

Owner/Operator Number:

Establishment Operations:

BioDerm Penis Clamp; KindKlamp

CLAMP, PENILE

FHA

1

876.5160

Gastroenterology

BIODERM, INC.

1063299

BIODERM, INC.

9032576

Specification Developer

Proprietary Name:

Classification Name:

Product Code:

Device Class:

Regulation Number:

Medical Specialty:

Registered Establishment Name:

Registered Establishment Number:

Owner/Operator:

Owner/Operator Number:

Establishment Operations:

BioPlus Skin Wipe

TAPE AND BANDAGE, ADHESIVE

KGX

1

880.5240

General Hospital

BIODERM, INC.

1063299

BIODERM, INC.

9032576

Specification Developer