



## BioDerm, Inc. FDA Establishment Registration & Device Listing 2019

**Establishment:** BIODERM, INC.  
12320 73<sup>rd</sup> 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:** 2019

**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; CathGrip Wing Seal;  
Fortitude, CathGrip SlipGrip**

**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:** 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 Urine Collection Bag 1,000 mL Sterile Fluid Pathway;**

**BioDerm Urine Collection Bag 2,000 mL Sterile Fluid Pathway**

BAG, URINE COLLECTION, LEG, FOR EXTERNAL USE, STERILE

FAQ

1

876.5250

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:

**FreeDerm Adhesive Remover**

SOLVENT, ADHESIVE TAPE

KOX

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878.4730

General & Plastic Surgery

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:

**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 with Integral Urine Collection Chamber; Safe n' Dry, Men's Liberty Acute, XLS**

DEVICE, PASTE-ON FOR INCONTINENCE, NON-STERILE

NOA

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876.5250

Gastroenterology

BIODERM, INC.

1063299

BIODERM, INC.

9032576

Contract Manufacturer; Manufacturer



COMPASSIONATE SOLUTIONS

**Proprietary Name:**

Classification Name:	<b>BioDerm Penis Clamp; Kind Klamp</b> 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:	<b>BioPlus Skin Wipe</b> 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