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

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| **Establishment:** | BIODERM, INC.<br>12320 73rd Court North<br>Largo, FL 33773 |
| **Registration Number:** | 1063299 |
| **FEI Number*:** | 3001949129 |
| **Status:** | Active |
| **Initial Distributor/Importer:** | Yes<br>*Note Firm May Have Additional Establishment Types.<br>Please Review Listings For Further Information. |
| **Date Of Registration Status:** | 2019 |
| **Owner/Operator:** | BIODERM, INC.<br>12320 73rd Court North<br>Largo, FL 33773 |
| **Owner/Operator Number:** | 9032576 |

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| **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** |
| 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 |

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| **Proprietary Name:** | **BioDerm Urine Collection Bag 1,000 mL Sterile Fluid Pathway; BioDerm Urine Collection Bag 2,000 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 |

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| **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 |

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

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| **Proprietary Name:** | **BioDerm Penis Clamp; Kind Klamp** |
| 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 |

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| **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 |