



Sheathing Technologies, Inc. (Establishment Registration #2950776) FDA Marketing Clearances

Product	510K Number	FDA Device Listing Doc. #	FDA Product Code	FDA Device Classification
Isoprene Ultrasound Probe Covers/Sheathes	K091828	D087179	ITX	Class II
Latex Non-Sterile & Sterile Ultrasound Probe Covers/Sheathes	K925869	D023911		
Latex Free (Polyurethane) Sheathes3D™ Viral Barrier Ultrasound Probe Covers/Sheathes	K153212	D271245		
Latex Free (Polyurethane) Non-Sterile Microseamed Ultrasound Probe Covers/Sheathes	K963831	D023918		
Latex Free (Polyurethane) Sterile Microseamed Ultrasound Probe Covers/Sheathes	K990175	D023923		
Needle Guides	K043425	D023939		
Colonoscope Cover	K100966	D112107	FDF & ODB	
Needle Guide Kits	n/a	D158194	OIJ	
Probe Cover Kits	n/a	D158199	OIP	
Non-Sterile Gel	K112827	D208621	MUI	
Sterile Gel	K130041	D208622	MUI	

SHEATHING TECHNOLOGIES, INC.
675 JARVIS DRIVE
MORGAN HILL, CA 95037
PHONE: 800-873-3776 FAX: 877-244-5048
WEBSITE: <http://www.sheathes.com> E-MAIL: info@sheathes.com