

US FDA 510 (k)

	Product Name	K Number	Listing Number	Product Code
1	Catheter Guide Wire	K120119	D182317	DQX
2	Sunmed™ Inflation Device	K133795	D247840	MAV
3	Sunmed™ High Pressure Line	K140356	D247841	DQO
4	Sunmed™ Haemostatic Valves	K153685	D277469	DTL/DQX
5	Sunmed™ Control Syringes	K160190	D283137	DXT
6	Sunmed™ disposable needles	Exempt	D339121	DRC
7	Sunmed™ Inflation Device	Exempt	D340291	PTM
8	Sunmed™ Disposable Angio-Closure Pads	K191827	D375315	DXC
9	Sunmed™ Manifold and Stopcocks	Exempt	D386476	DTL
10	Sunmed™ disposable towel/sheet clips	Exempt	D386482	GDO
11	Sunmed™ Protective face shield	Exempt	D415883	LYU
12	Sunmed™ guidewire torque device	Exempt	D417881	PTL