

## Device Schedule: Class III and Class IIb devices

<b>Class III</b>	<b>Intended Purpose</b>
Amplatz Goose Neck™ Snare Kit	See MDR 772711
Amplatz Goose Neck™ MicroSnare Kit	
Mo.Ma Ultra Cerebral Protection Device	See MDR 734887
Protégé™ RX Self-expanding Carotid Stent System and Protégé™ RX Tapered Self-expanding Carotid Stent System	See MDR 734885
<b>Class IIb, Implantable</b>	<b>Intended Purpose</b>
EverFlex Self-Expanding Peripheral Stent with Entrust Delivery System	MDR 734893
Protégé EverFlex Self-Expanding Peripheral Stent System	MDR 734894
Protégé™ GPS™ Self-expanding Peripheral Stent System	MDR 734890
Visi-Pro™ Balloon-expandable Peripheral Stent System	MDR 772705
<b>Class IIb</b>	<b>Intended Purpose</b>
HawkOne Directional Atherectomy System – Cutter Driver	The intended purpose of the HawkOne directional atherectomy system is to restore blood flow by removing atherosclerotic calcified and non-calcified plaque from peripheral arteries to maximize luminal gain.
Ellipsys Vascular Access System	The Ellipsys catheter and power controller are intended to be used as a part of the Ellipsys System for the percutaneous creation of a vascular anastomosis between adjacent blood vessels.

## Device Schedule: Class IIa, Custom-made and other devices

<b>Device(s)</b>	<b>Risk Classification</b>
Peripheral Vascular Catheters and Introducers	Class IIa