

Device Schedule: Class III and Class IIb devices

Class III	Intended purpose
Apollo / Aperi NC / Origin NC Balloon Dilatation Catheters	See MDR 752505
Artimes / Aperi SC / Origin SC Balloon Dilatation Catheters	See MDR 752506
Mars PTCA Balloon Dilatation Catheters	See MDR 796971
Mars NC PTCA Balloon Dilatation Catheters	See MDR 796973
RevoEdge High Pressure Cutting Balloon Dilatation Catheters	See MDR 805974

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

Device(s)	Risk Classification
PTA Balloon Dilatation Catheters	Class IIa