

# The Medical Devices Special Access Program in Canada: A Scoping Study

## Programme canadien d'accès spécial aux instruments médicaux : étude de l'étendue

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### Appendix 4. Medical Devices Obtained via Special Access Program Authorization

Device manufacturer/vendor	Device name	Medical specialty
Abbott Laboratories	MitraClip	Cardiovascular
Abbott Medical Optics (acquired Visiogen)	Synchrony	Ophthalmology
Abiomed	Impella Right Direct	Cardiovascular
Abiomed	Impella Right Peripheral	Cardiovascular
AGA Medical Corporation	Amplatzer Cardiac Plug	Cardiovascular
AGA Medical Corporation	Amplatzer Membranous VSD Occluder 2	Cardiovascular
Allergan (see also Inamed)	Style 410	General and plastic surgery
Bard	Recovery	Cardiovascular
Bard Peripheral Vascular	Fluency Plus	Cardiovascular
Berlin Heart	Berlin Heart Excor Pediatric	Cardiovascular
Biosense Webster	(Not stated)	Cardiovascular
Boston Scientific	Watchman	Cardiovascular
Cook Medical	Custom-made stent graft	Cardiovascular
CoreValve	CoreValve revalving system	Cardiovascular
Correx	(Not stated)	Cardiovascular
Edwards Lifesciences	Ascendra transapical catheter	Cardiovascular
Edwards Lifesciences	Cribier Edwards	Cardiovascular
Edwards Lifesciences	Forma Repair System	Cardiovascular
Edwards Lifesciences	Fortis	Cardiovascular
Edwards Lifesciences	RetroFlex delivery catheter	Cardiovascular
Edwards Lifesciences	RetroFlex II delivery system	Cardiovascular

Device manufacturer/vendor	Device name	Medical specialty
Edwards Lifesciences	Sapien	Cardiovascular
Edwards Lifesciences	Sapien XT	Cardiovascular
Edwards Lifesciences	Sapien 3	Cardiovascular
Ev3 Endovascular Inc	Pipeline Embolization Device	Neurology
Flowcardia	CROSSER system	Cardiovascular
Fresenius Kabi	Freka Pexact	Gastroenterology and urology
HeartWare	HVAD	Cardiovascular
Inamed Aesthetics (see also Allergan)	Style 410	General and plastic surgery
Innogenetics	Inno-LIA HIV I/II	Microbiology
MDMI Technologies	Thermablate	Obstetrics and gynecology
Medtronic (see CoreValve)	CoreValve	Cardiovascular
Medtronic	ATS 3f	Cardiovascular
Medtronic	ATS Enable Model 6000	Cardiovascular
Medtronic	Talent	Cardiovascular
Mentor	(Not stated)	General and plastic surgery
Neovasc Inc	Tiara system	Cardiovascular
NMT Medical	Recovery	Cardiovascular
NuMed Inc	Cheatham-Platinum stent	Cardiovascular
Ophtec	Artisan iris-claw	Ophthalmology
PhysIOL	FineVision	Ophthalmology
Polymekon	Bio-Alcamid	General and plastic surgery
St Jude Medical	Amplatzer Vascular Plug III	Cardiovascular
St Jude Medical	Amulet	Cardiovascular
St Jude Medical	Portico valve system	Cardiovascular
Standard Diagnostics	SD Bioline Syphilis 3.0 Test	Microbiology
Target Therapeutics	TriSpan	Neurology
Teleflex Medical	Rusch Trachflex Plus	Anaesthesiology
Thoratec	Aria	Cardiovascular
V-Wave Ltd	V-Wave	Cardiovascular
Visiogen (see Abbott Medical Optics)	Synchrony	Ophthalmology
William Cook Europe	Cook Zenith TX2	Cardiovascular
Zeiss	AT LISA 809	Ophthalmology