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

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

ROLAND K. MAIER, DEVIDAS MENON AND TANIA STAFINSKI

Appendix 4. Medical Devices Obtained via Special Access Program Authorization

<table>
<thead>
<tr>
<th>Device manufacturer/vendor</th>
<th>Device name</th>
<th>Medical specialty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott Laboratories</td>
<td>MitraClip</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Abbott Medical Optics (acquired Visiogen)</td>
<td>Synchrony</td>
<td>Ophthalmology</td>
</tr>
<tr>
<td>Abiomed</td>
<td>Impella Right Direct</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Abiomed</td>
<td>Impella Right Peripheral</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>AGA Medical Corporation</td>
<td>Amplatzer Cardiac Plug</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>AGA Medical Corporation</td>
<td>Amplatzer Membranous VSD Occluder 2</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Allergan (see also Inamed)</td>
<td>Style 410</td>
<td>General and plastic surgery</td>
</tr>
<tr>
<td>Bard</td>
<td>Recovery</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Bard Peripheral Vascular</td>
<td>Fluency Plus</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Berlin Heart</td>
<td>Berlin Heart Excor Pediatric</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Biosense Webster</td>
<td>(Not stated)</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Boston Scientific</td>
<td>Watchman</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Cook Medical</td>
<td>Custom-made stent graft</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>CoreValve</td>
<td>CoreValve revalving system</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Correx</td>
<td>(Not stated)</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Edwards Lifesciences</td>
<td>Ascendra transapical catheter</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Edwards Lifesciences</td>
<td>Cribier Edwards</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Edwards Lifesciences</td>
<td>Forma Repair System</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Edwards Lifesciences</td>
<td>Fortis</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Edwards Lifesciences</td>
<td>RetroFlex delivery catheter</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Edwards Lifesciences</td>
<td>RetroFlex II delivery system</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Device manufacturer/vendor</td>
<td>Device name</td>
<td>Medical specialty</td>
</tr>
<tr>
<td>---------------------------</td>
<td>-------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>Edwards Lifesciences</td>
<td>Sapien</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Edwards Lifesciences</td>
<td>Sapien XT</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Edwards Lifesciences</td>
<td>Sapien 3</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Ev3 Endovascular Inc</td>
<td>Pipeline Embolization Device</td>
<td>Neurology</td>
</tr>
<tr>
<td>Flowcardia</td>
<td>CROSSER system</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Fresenius Kabi</td>
<td>Freka Pexact</td>
<td>Gastroenterology and urology</td>
</tr>
<tr>
<td>HeartWare</td>
<td>HVAD</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Inamed Aesthetics (see also Allergan)</td>
<td>Style 410</td>
<td>General and plastic surgery</td>
</tr>
<tr>
<td>Innogenetics</td>
<td>Inno-LIA HIV I/II</td>
<td>Microbiology</td>
</tr>
<tr>
<td>MDMI Technologies</td>
<td>Thermablate</td>
<td>Obstetrics and gynecology</td>
</tr>
<tr>
<td>Medtronic (see CoreValve)</td>
<td>CoreValve</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Medtronic</td>
<td>ATS 3f</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Medtronic</td>
<td>ATS Enable Model 6000</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Medtronic</td>
<td>Talent</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Mentor</td>
<td>(Not stated)</td>
<td>General and plastic surgery</td>
</tr>
<tr>
<td>Neovasc Inc</td>
<td>Tiara system</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>NMT Medical</td>
<td>Recovery</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>NuMed Inc</td>
<td>Cheatham-Platinum stent</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Ophtec</td>
<td>Artisan iris-claw</td>
<td>Ophthalmology</td>
</tr>
<tr>
<td>PhysIOL</td>
<td>FineVision</td>
<td>Ophthalmology</td>
</tr>
<tr>
<td>Polymekon</td>
<td>Bio-Alcamid</td>
<td>General and plastic surgery</td>
</tr>
<tr>
<td>St Jude Medical</td>
<td>Amplatzer Vascular Plug III</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>St Jude Medical</td>
<td>Amulet</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>St Jude Medical</td>
<td>Portico valve system</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Standard Diagnostics</td>
<td>SD Bioline Syphilis 3.0 Test</td>
<td>Microbiology</td>
</tr>
<tr>
<td>Target Therapeutics</td>
<td>TriSpan</td>
<td>Neurology</td>
</tr>
<tr>
<td>Teleflex Medical</td>
<td>Rusch Trachflex Plus</td>
<td>Anaesthesiaology</td>
</tr>
<tr>
<td>Thoratec</td>
<td>Aria</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>V-Wave Ltd</td>
<td>V-Wave</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Visiogen (see Abbott Medical Optics)</td>
<td>Synchrony</td>
<td>Ophthalmology</td>
</tr>
<tr>
<td>William Cook Europe</td>
<td>Cook Zenith TX2</td>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Zeiss</td>
<td>AT LISA 809</td>
<td>Ophthalmology</td>
</tr>
</tbody>
</table>