



DEVICE DETAILS

NAME OF DEVICE	APYX ONE™ CONSOLE AND RENUVION® MICRO HANDPIECE
ESTABLISHMENT NAME	FREYRSOLUTIONS SDN. BHD.
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC5174025-211616
BRAND NAME	APYX-ONE APYX-10-MICRO
MEDICAL DEVICE CATEGORY	MD 1104 - Active surgical devices
DEVICE GROUPING TYPE	SYSTEM
DEVICE DESCRIPTION	<p>Apyx One™ Console: The Apyx One™ Console (APYX-ONE), is an electrosurgical device that delivers radiofrequency (RF) energy to cut and coagulate soft tissue. It can also deliver Helium Plasma energy for cutting, coagulation, and ablation of soft tissue. Like the predicate, the Apyx One™ Console provides standard electrosurgical energy and Helium Plasma energy, and there are no changes to the intended use, performance specifications, electrosurgical modes, output power waveforms, or maximum power settings. Renuvion® Micro Handpiece: The Renuvion® Micro handpiece is a sterile, single use electrosurgical (monopolar) device intended to be used in conjunction with the Apyx One Electrosurgical Generator for the percutaneous delivery of radiofrequency and helium plasma energy to soft tissue. When connected to the Apyx One Generator, the device operates at an adjustable power of up to 12 W (expressed as 0 – 30% where 30% is 12 W) and an adjustable helium gas flow of 1 – 1.5 L/Min. Radiofrequency energy is delivered to the handpiece by the generator and used to energize the electrode. When helium gas is passed over the energized electrode, a helium plasma is generated for soft tissue coagulation/contraction. The Renuvion® Micro Handpiece has a non-extendable electrode to generate helium plasma. The handpiece features a low-profile shaft that is 10cm in length. The distal end of the shaft and tip has a 2mm outer diameter that tapers down to 1.5mm for the remaining length of the shaft.</p>
DEVICE INTENDED PURPOSE	<p>Apyx One™ Console: The Apyx One™ Console is indicated for the delivery of radiofrequency energy and/or helium plasma to cut, coagulate and ablate soft tissue during open and laparoscopic surgical procedures. The helium plasma portion of the generator can be used only with dedicated Renuvion/J-Plasma handpieces. Renuvion® Micro Handpiece: The Renuvion® Micro Handpiece is intended for the delivery of radiofrequency energy and/or helium plasma where coagulation/contraction of soft tissue is needed. Soft tissue includes subcutaneous tissue. The Renuvion® Micro Handpiece is compatible with the Apyx One™ Console Generator, owned by Apyx Medical.</p>
VALIDITY DATE OF REGISTRATION	18/09/2025 - 17/09/2030

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	APYX ONE™ CONSOLE	APYX-ONE
2	Renuvion® Micro Handpiece (10 Cm)	APYX-10-MICRO
3	Renuvion / J-Plasma Precise Open Handpiece	APYX-044-BPS
4	Renuvion / J-Plasma Precise Open Handpiece	APYX-150-BPS
5	Renuvion Precise Handpiece	APYX-270BPP
6	Renuvion APR Handpiece	APYX-15-SP
7	Renuvion APR Handpiece	APYX-15-TP
8	Renuvion APR Handpiece	APYX-27-TP
9	Renuvion Dermal Handpiece	APYX-044-DERM
10	Monopolar Footswitch	APYX-1253B
11	Bipolar Footswitch	APYX-1254B
12	Renuvion/J-Plasma Dual Pedal Footswitch	APYX-JPDFS
13	Disposable Split Pad Return Electrodes	APYX-ESREC
14	Helium Gas Regulator	APYX-HGS
15	Helium Gas Regulator with digital pressure sensor	APYX-HGSD