

510(k) Premarket Notification



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Device Classification Name	Stimulator, Muscle, Powered, For Muscle Conditioning ²²
510(K) Number	K190038
Device Name	Xbody Newave USA
Applicant	XBody Hungary Kft. Gyorgy Aladar U. 35-39 Budapest, HU 1125
Applicant Contact	Peter Tar
Correspondent	Biomedical Regulatory Consulting 9203 Hwy 6 South, Suite 124 Houston, TX 77083
Correspondent Contact	R. William Soller
Regulation Number	890.5850 ²³
Classification Product Code	NGX ²⁴
Date Received	01/08/2019
Decision Date	04/05/2019
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Physical Medicine
510k Review Panel	Physical Medicine
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

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