

# 510(k) Premarket Notification

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<b>Device Classification Name</b>	<a href="#">Powered Laser Surgical Instrument</a>
<b>510(K) Number</b>	K120561
<b>Device Name</b>	NEUROBLATE SYSTEM
<b>Applicant</b>	MONTERIS MEDICAL, INC. 100 - 78 Innovation Drive Winnipeg,
<b>Contact</b>	Jeff Wilson
<b>Regulation Number</b>	<a href="#">878.4810</a>
<b>Classification Product Code</b>	<a href="#">GEX</a>
<b>Subsequent Product Code</b>	<a href="#">HAW</a>
<b>Date Received</b>	02/24/2012
<b>Decision Date</b>	04/01/2013
<b>Decision</b>	Substantially Equivalent (SE)
<b>Classification Advisory Committee</b>	General & Plastic Surgery
<b>Review Advisory Committee</b>	General & Plastic Surgery
<b>Type</b>	Traditional
<b>Reviewed By Third Party</b>	No
<b>Expedited Review</b>	No
<b>Combination Product</b>	No

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