510(k) Premarket Notification

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

Page Last Updated: 04/01/2013
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