

<b>Device Classification Name</b>	<u>Catheter, Percutaneous</u>
<b>510(K) Number</b>	K143608
<b>Device Name</b>	NovaCross Microcatheter
<b>Applicant</b>	Nitiloop Ltd. 8 Hamada St. P.O.Box 12892 Herzliya, IL 46733
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<b>Regulation Number</b>	<u>870.1250</u>
<b>Classification Product Code</b>	<u>DQY</u>
<b>Date Received</b>	12/19/2014
<b>Decision Date</b>	05/04/2015
<b>Decision</b>	Substantially Equivalent (SESE)
<b>Regulation Medical Specialty</b>	Cardiovascular
<b>510k Review Panel</b>	Cardiovascular
<b>Summary</b>	<u>Summary</u>
<b>Type</b>	Traditional
<b>Reviewed By Third Party</b>	No
<b>Combination Product</b>	No