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**510(k) Premarket Notification Database**

<b>Device Classification Name</b>	<a href="#">Stopcock, I.V. Set</a>
<b>510(K) Number</b>	K053405
<b>Device Name</b>	BACSTOP
<b>Applicant</b>	ELCAM MEDICAL A.C.A.L. Kibbutz Bar-Am D.N. Merom Hagalil, IS 13860
<b>Contact</b>	Tali Hazan
<b>Regulation Number</b>	<a href="#">880.5440</a>
<b>Classification Product Code</b>	<a href="#">FMG</a>
<b>Date Received</b>	12/07/2005
<b>Decision Date</b>	05/11/2006
<b>Decision</b>	Substantially Equivalent (SE)
<b>Classification Advisory Committee</b>	General Hospital
<b>Review Advisory Committee</b>	General Hospital
<b>Statement/Summary/Purged Status</b>	Summary Only
<b>Summary</b>	<a href="#">Summary</a>
<b>Type</b>	Traditional
<b>Reviewed By Third Party</b>	No
<b>Expedited Review</b>	No

Database Updated 08/06/2008

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