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510(k) Premarket Notification Database

Device Classification Name	stopcock, i.v. set
510(k) Number	K082106
Device Name	ELCAM ANTIMICROBIAL CLOSED STOPCOCKS (DSS AND TSS)
Applicant	ELCAM MEDICAL A.C.A.L. kibbutz bar-am d.n. merom hagalil,
Contact	tali hazan
Regulation Number	880.5440
Classification Product Code	FMG
Date Received	07/25/2008
Decision Date	10/02/2008
Decision	substantially equivalent (SE)
Classification Advisory Committee	General Hospital
Review Advisory Committee	General Hospital
Statement/Summary/Purged Status	Summary only
summary	summary
Type	Special
Reviewed by Third Party	No
Expedited Review	No

Database Updated 03/06/2009

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