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510(k) Premarket Notification Database

Device Classification Name	Clip, Implantable
510(K) Number	K031623
Regulation Number	878.4300
Device Name	Modification To Coalescent Surgical U-Clip And Ac
Applicant	Coalescent Surgical 559 East Weddell Dr. Sunnyvale, CA 94089
Contact	Michael A Daniel
Product Code	FZP
Date Received	06/04/2003
Decision Date	07/03/2003
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	General & Plastic Surgery
Review Advisory Committee	General & Plastic Surgery
Statement/Summary/Purged Status	Summary Only
Summary	Summary
Type	Special
Reviewed By Third Party	No
Expedited Review	No

Database Updated 1/05/2004

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