510(k) Premarket Notification Database

Device Classification Name	Clip, Implantable
510(K) Number	K003958
Regulation Number	878.4300
Device Name	Coalescent U-Clip Delivery And Disposal Device
Applicant	Coalescent Surgical 559 East Weddell Dr. Sunnyvale, CA 94089
Contact	Michael A Daniel
Product Code	FZP
Date Received	12/21/2000
Decision Date	02/06/2001
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	General & Plastic Surgery
Review Advisory Committee	Neurology
Statement/Summary/Purged Status	Summary Only
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

Database Updated 1/05/2004