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510(k) Premarket Notification Database

Device Classification Name Clip, Implantable

K024366 510(K) Number **Regulation Number** 878.4300

Coalescent Surgical U-Clip And **Device Name**

Accessories

Coalescent Surgical 559 East Weddell Dr. **Applicant** Sunnyvale, CA 94089

Summary Only

Michael A Daniel Contact

FZP Product Code

Date Received 12/31/2002 01/17/2003 **Decision Date**

Decision Substantially Equivalent (SE)

Classification Advisory

Committee

General & Plastic Surgery **Review Advisory Committee** General & Plastic Surgery

Statement/Summary/Purged

Status

Summary Summary Special **Type** No

Reviewed By Third Party Expedited Review No

Database Updated 1/05/2004

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