



[FDA Home Page](#) | [CDRH Home Page](#) | [Search](#) | [CDRH A-Z Index](#) | [Contact CDRH](#)



[510\(k\)](#) | [Registration](#) | [Listing](#) | [Adverse Events](#) | [PMA](#) | [Classification](#) | [CLIA](#)  
[CFR Title 21](#) | [Advisory Committees](#) | [Assembler](#) | [NHRIC](#) | [Guidance](#) | [Standards](#)

[New Search](#)

[Back To Search Results](#)

### 510(k) Premarket Notification Database

<b>Device Classification Name</b>	<a href="#">Clip, Implantable</a>
<b>510(K) Number</b>	K003958
<b>Regulation Number</b>	<a href="#">878.4300</a>
<b>Device Name</b>	Coalescent U-Clip Delivery And Disposal Device
<b>Applicant</b>	<a href="#">Coalescent Surgical</a> 559 East Weddell Dr. Sunnyvale, CA 94089
<b>Contact</b>	Michael A Daniel
<b>Product Code</b>	FZP
<b>Date Received</b>	12/21/2000
<b>Decision Date</b>	02/06/2001
<b>Decision</b>	Substantially Equivalent (SE)
<b>Classification Advisory Committee</b>	General & Plastic Surgery
<b>Review Advisory Committee</b>	Neurology
<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 1/05/2004

[CDRH Home Page](#) | [CDRH A-Z Index](#) | [Contact CDRH](#) | [Accessibility](#) | [Disclaimer](#)  
[FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#) | [HHS Home Page](#)

Center for Devices and Radiological Health / CDRH