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### 510(k) Premarket Notification Database

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|--|--|
| <b>Device Classification Name</b>        | <a href="#">Clip, Implantable</a>  |
| <b>510(K) Number</b>                     | K040821  |
| <b>Regulation Number</b>                 | <a href="#">878.4300</a>   |
| <b>Device Name</b>                       | Coalescent Surgical U-Clip And Accessories   |
| <b>Applicant</b>                         | <a href="#">Coalescent Surgical</a><br>559 East Weddell Dr.<br>Sunnyvale, CA 94089 |
| <b>Contact</b>                           | Michael A Daniel   |
| <b>Product Code</b>                      | FZP  |
| <b>Date Received</b>                     | 03/30/2004   |
| <b>Decision Date</b>                     | 04/23/2004   |
| <b>Decision</b>                          | Substantially Equivalent (SE)  |
| <b>Classification Advisory Committee</b> | General & Plastic Surgery  |
| <b>Review Advisory Committee</b>         | General & Plastic Surgery  |
| <b>Statement/Summary/Purged Status</b>   | Summary Only   |
| <b>Type</b>                              | Traditional  |
| <b>Reviewed By Third Party</b>           | No   |
| <b>Expedited Review</b>                  | No   |

Database Updated 5/7/2004

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