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### 510(k) Premarket Notification Database

|                                          |                                                                                    |
|------------------------------------------|------------------------------------------------------------------------------------|
| <b>Device Classification Name</b>        | <a href="#">Clip, Implantable</a>                                                  |
| <b>510(K) Number</b>                     | K012317                                                                            |
| <b>Regulation Number</b>                 | <a href="#">878.4300</a>                                                           |
| <b>Device Name</b>                       | Coalescent Surgical U-Clip                                                         |
| <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>                     | 07/23/2001                                                                         |
| <b>Decision Date</b>                     | 08/31/2001                                                                         |
| <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>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

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