

**K893856 ABUSCREEN ONTRAK POS. REF. CONTROL FOR MORPHINE**Aug 3, 1989  
70 days to decisionK893856 · Product code: **LAS** · Toxicology  
Source: <https://www.510kdatabase.net/k893856/>**SUBMISSION DETAILS**

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|                       |                                       |
|-----------------------|---------------------------------------|
| Decision              | Substantially Equivalent (Cleared)    |
| Submission type       | Traditional                           |
| Device classification | Drug Specific Control Materials (LAS) |
| Date received         | May 25, 1989                          |
| Decision date         | Aug 3, 1989                           |
| Days to decision      | 70 days                               |
| Third-party review    | No                                    |
| Combination product   | No                                    |
| PCCP authorized       | No                                    |

**APPLICANT**

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|----------------|---|
| Company        | <b>Roche Diagnostic Systems, Inc.</b>     |
| Location       | Mchenry, IL, US                           |
| Contact        | ALEX WESOLOWSKI                           |
| 510(k) history | 296 submissions · 296 cleared · 1983-1999 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k893856/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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