

K012138 MODIFICATION TO ACIS (AUTOMATED CELLULAR IMAGING SYSTEM)Sep 30, 2002
447 days to decisionK012138 · Product code: **MYA** · Pathology
Source: <https://www.510kdatabase.net/k012138/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Immunohistochemistry Antibody Assay, Estrogen Receptor (MYA) |
| Date received | Jul 10, 2001 |
| Decision date | Sep 30, 2002 |
| Days to decision | 447 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|--|
| Company | Chroma Vision Medical Systems, Inc. |
| Location | San Juan Capistrano, CA, US |
| Contact | DAVID DAVIS |
| 510(k) history | 3 submissions · 3 cleared · 1999-2003 |

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