

**K991486 ULTRA-CBX**Nov 5, 1999  
191 days to decisionK991486 · Product code: **DWZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k991486/>**SUBMISSION DETAILS**

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|                       |                                      |
|-----------------------|--------------------------------------|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional                          |
| Device classification | Device, Biopsy, Endomyocardial (DWZ) |
| Date received         | Apr 28, 1999                         |
| Decision date         | Nov 5, 1999                          |
| Days to decision      | 191 days                             |
| Third-party review    | No                                   |
| Summary / Statement   | Summary                              |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Medcanica, Inc.</b>                |
| Location       | Miami, FL, US                         |
| Contact        | AL WEISENBORN                         |
| 510(k) history | 5 submissions · 5 cleared · 1999-2001 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k991486/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 21, 2026