

K052043 3.8MM CS FACET COMPRESSION DEVICEOct 17, 2005
81 days to decisionK052043 · Product code: **MRW** · Orthopedic
Source: <https://www.510kdatabase.net/k052043/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Facet Screw Spinal Device (MRW)
Date received	Jul 28, 2005
Decision date	Oct 17, 2005
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Triage Medical, Inc.
Location	Irvine, CA, US
Contact	GAYLE HIROTA
510(k) history	11 submissions · 11 cleared · 2001-2006

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k052043/> Data sourced from FDA 510(k) public records (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. - Generated May 19, 2026