

**K043249 ATRION NEEDLEWISE LARGE-BORE SHARPS
SECURING DEVICE**May 25, 2005
183 days to decisionK043249 · Product code: **FMI** · General Hospital
Source: <https://www.510kdatabase.net/k043249/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Nov 23, 2004
Decision date	May 25, 2005
Days to decision	183 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Atrion Medical Products, Inc.
Location	Arab, AL, US
Contact	DAN CLARK
510(k) history	9 submissions · 9 cleared · 1997-2006

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k043249/>; 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 25, 2026