

**K933242 SOFAMOR ORTHOPAEDIC INSTRUMENTS**Jan 28, 1994  
210 days to decisionK933242 · Product code: **LXH** · Orthopedic  
Source: <https://www.510kdatabase.net/k933242/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Manual Surgical Instrument (LXH)
Date received	Jul 2, 1993
Decision date	Jan 28, 1994
Days to decision	210 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Danek Medical, Inc.</b>
Location	Mchenry, IL, US
Contact	BRIAN GOODEN
510(k) history	56 submissions · 47 cleared · 1981-2000

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k933242/> 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