

**K943819 ISOLA ANTERIOR SYSTEM**Feb 9, 1995  
188 days to decisionK943819 · Product code: **KWQ** · Orthopedic  
Source: <https://www.510kdatabase.net/k943819/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Aug 5, 1994
Decision date	Feb 9, 1995
Days to decision	188 days
Third-party review	No

**APPLICANT**

---

Company	<b>Acromed Corp.</b>
Location	Cleveland, OH, US
Contact	JOYCE THOMAS
510(k) history	41 submissions · 22 cleared · 1984-1998

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k943819/>; 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