

K080588 SCIENT'X TRIBECA VBRMay 30, 2008
88 days to decisionK080588 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k080588/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Mar 3, 2008
Decision date	May 30, 2008
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Scient&apos;X USA, Inc.
Location	Round Rock, TX, US
Contact	JOHN SANDERS
510(k) history	4 submissions · 4 cleared · 2003-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k080588/> 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