FDA 510(k) Premarket Notification

K080588 SCIENT'X TRIBECA VBR

CLEARED

May 30, 2008
88 days to decision

K080588 · 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'X USA, Inc.**
Location	Round Rock, TX, US
Contact	JOHN SANDERS
510(k) history	4 submissions · 4 cleared · 2003-2009