FDA 510(k) Premarket Notification

CLEARED

K100042 DIFUSION TECHNOLOGIES XIPHOS INTERBODY FUSION SYSTEM

Oct 1, 2010
266 days to decision

K100042 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k100042/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Jan 8, 2010
Decision date	Oct 1, 2010
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Difusion Technologies**
Location	Austin, TX, US
Contact	JAMI HAFIZ
510(k) history	3 submissions · 3 cleared · 2010-2019