

K100305 ETURN SPINAL IMPLANT MODEL ETURN XX-12Jul 21, 2011
533 days to decisionK100305 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k100305/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Feb 3, 2010
Decision date	Jul 21, 2011
Days to decision	533 days
Third-party review	No
Summary / Statement	Summary
Other names	ETURN XX-16 WHERE XX=07, 09, 11, 13, OR 15 AND ETURN XX-12 K; ETURN XX-16 K WHER

APPLICANT

Company	Icotec
Location	Minneapolis, MN, US
Contact	BARBARA ATZENHOEFER STEGMEIER
510(k) history	1 submissions · 1 cleared · 2011-2011

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