

**K143572 Intersomatic Cervical Device - DICOM PEEK,
Intersomatic Intervertebral Space Maintenance Device - DIMEI
PEEK, Intersomatic Transforaminal - TLIF PEEK**Jun 10, 2015
175 days to decisionK143572 · Product code: **ODP** · Orthopedic
Source: <https://www.510kdatabase.net/k143572/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Dec 17, 2014
Decision date	Jun 10, 2015
Days to decision	175 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Osteomed Implantex, Ltda
Location	Rio Claro - Sp, BR
Contact	Niderdani Ragonha
510(k) history	3 submissions · 3 cleared · 2015-2016

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