

**K150607 Osseoflex SB Straight Balloon, 10g/4ml, Osseoflex SB
Straight Balloon, 10g/2ml**Apr 9, 2015
30 days to decisionK150607 · Product code: **NDN** · Orthopedic
Source: <https://www.510kdatabase.net/k150607/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Mar 10, 2015
Decision date	Apr 9, 2015
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Osseon, LLC
Location	Santa Rosa, CA, US
Contact	Keith Burger
510(k) history	3 submissions · 3 cleared · 2014-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150607/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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