

K162453 13G InterV Kyphoplasty Catheter (Micro) and 11G InterV Kyphoplasty Catheter (Mini-Flex)

Nov 1, 2016
61 days to decision

K162453 · Product code: **NDN** · Orthopedic
Source: <https://www.510kdatabase.net/k162453/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Sep 1, 2016
Decision date	Nov 1, 2016
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pan Medical , Ltd.
Location	Gloucester, Gloucestershire, GB
Contact	Jennie Budding
510(k) history	3 submissions · 3 cleared · 2014-2016

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k162453/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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