

K130402 SPIDER SYSTEM KOLIBRI CEMENT NEEDLE

Apr 1, 2013
41 days to decision

K130402 · Product code: **NDN** · Orthopedic
Source: <https://www.510kdatabase.net/k130402/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Feb 19, 2013
Decision date	Apr 1, 2013
Days to decision	41 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sintea Plustek, LLC
Location	Miami Beach, FL, US
Contact	RICH JANSEN
510(k) history	3 submissions · 3 cleared · 2012-2014

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k130402/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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