

K231340 Renova Spine Balloon CatheterOct 30, 2023
174 days to decisionK231340 · Product code: **NDN** · Orthopedic
Source: <https://www.510kdatabase.net/k231340/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	May 9, 2023
Decision date	Oct 30, 2023
Days to decision	174 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Biopsybell S.R.L.
Location	Verona, NJ, US
Contact	Carlo Ricca Prandi Bellini
510(k) history	4 submissions · 4 cleared · 2014-2023

REGULATORY CONSULTANT

Consulting firm	Maytal Doo
Contact	Maurizio Pantaleoni

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231340/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026