CLEARED

Jan 11, 2021
54 days to decision

K203397 Marrow-Pack (white)- 11gauge/10cm or 13gauge/10cm, Marrow-Tray (red)- 11gauge/10cm or 13gauge/10cm, Marrow-Set (violet)- 11gauge/10cm or 13gauge/10cm, Marrow-kit (grey)- 11gauge/10cm or 13gauge/10cm, Marrow-Stem (green)- 11gauge/10cm or 13gauge/10cm

K203397 · Product code: **KNW** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k203397/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Nov 18, 2020
Decision date	Jan 11, 2021
Days to decision	54 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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k203397/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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