FDA 510(k) Premarket Notification

CLEARED

K202012 Mammotome Revolve Dual Vacuum Assisted Biopsy (VAB) System

Aug 18, 2020
28 days to decision

K202012 · Product code: **KNW** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k202012/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Jul 21, 2020
Decision date	Aug 18, 2020
Days to decision	28 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Devicor Medical Products, Inc.**
Location	Cincinnati, OH, US
Contact	Gwendolyn P. Payne
510(k) history	16 submissions · 16 cleared · 2012-2026

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov