FDA 510(k) Premarket Notification

K221676 Exsalta

CLEARED

Sep 16, 2022
99 days to decision

K221676 · Product code: **BTA** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k221676/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Portable, Aspiration (manual Or Powered) (BTA)
Date received	Jun 9, 2022
Decision date	Sep 16, 2022
Days to decision	99 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Drw Medical**
Location	Aston, PA, US
Contact	Dan Tatum
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**ProMedic Consulting, LLC**
Contact	Paul Dryden

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