

K153138 Cerdak BasicJun 23, 2017
602 days to decisionK153138 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k153138/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Oct 30, 2015
Decision date	Jun 23, 2017
Days to decision	602 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bu Polysciences Equipment & Trading, LLC
Location	North Bethesda, MD, US
Contact	N. T. UMAMAHESWARAN
510(k) history	1 submissions · 1 cleared · 2017-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153138/> 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 June 1, 2026