

K180643 MedCu Antibacterial Wound Dressings with Copper-Oxide (MedCu ABWDs)Nov 23, 2018
256 days to decisionK180643 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k180643/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Mar 12, 2018
Decision date	Nov 23, 2018
Days to decision	256 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medcu Technologies , Ltd.
Location	Herzlia, IL
Contact	Gadi Borkow
510(k) history	1 submissions · 1 cleared · 2018-2018

REGULATORY CONSULTANT

Consulting firm	Talmed , Ltd.
Contact	Tali Hazan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180643/>; 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 28, 2026