

K251093 Bonvadis®Jun 9, 2025
60 days to decisionK251093 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k251093/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Apr 10, 2025
Decision date	Jun 9, 2025
Days to decision	60 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Oneness Biotech Co., Ltd.
Location	Taipei, TW
Contact	Angel Hsieh
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251093/> 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 May 14, 2026