

K261638 Bonvadis®Jun 17, 2026
30 days to decisionK261638 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k261638/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dressing, Wound, Drug (FRO)
Date received	May 18, 2026
Decision date	Jun 17, 2026
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Oneness Biotech Co., Ltd.
Location	Taipei, TW
Contact	Angel Hsieh
510(k) history	2 submissions · 2 cleared · 2025-2026

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