

K202929 NexpowderSep 16, 2022
717 days to decisionK202929 · Product code: **QAU** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k202929/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Device For Endoscopic Gastrointestinal Use (QAU)
Date received	Sep 29, 2020
Decision date	Sep 16, 2022
Days to decision	717 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nextbiomedical Co., Ltd.
Location	Incheon, KR
Contact	Jin Young Lee
510(k) history	2 submissions · 2 cleared · 2022-2024

REGULATORY CONSULTANT

Consulting firm	K-Bio Solutions
Contact	Kyungyoon Kang

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

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