

**K211570 Zeolite Hemostatic Gauze**Feb 10, 2022  
265 days to decisionK211570 · Product code: **QSY** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k211570/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Wound Dressing Without Thrombin Or Other Biologics (QSY)
Date received	May 21, 2021
Decision date	Feb 10, 2022
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hangzhou Zeo-Innov Life Technology Co., Ltd.</b>
Location	Hangzhou, CN
Contact	Lijuan Zhao
510(k) history	2 submissions · 2 cleared · 2022-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mid-Link Consulting Co, Ltd.</b>
Contact	Diana Hong

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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