

K232216 Hemoblock_S (Prescription)Apr 19, 2024
268 days to decisionK232216 · Product code: **QSY** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k232216/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Wound Dressing Without Thrombin Or Other Biologics (QSY)
Date received	Jul 26, 2023
Decision date	Apr 19, 2024
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Hemoblock_S (OTC)

APPLICANT

Company	Incore Co., Ltd.
Location	Daegu, KR
Contact	Jae-Hun Lee
510(k) history	6 submissions · 6 cleared · 2022-2024

REGULATORY CONSULTANT

Consulting firm	KMC, Inc.
Contact	Milly An

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232216/> 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 13, 2026