

**K242664 gentleheel® Adult Incision Device**Nov 5, 2024  
62 days to decisionK242664 · Product code: **FMK** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k242664/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature (FMK)
Date received	Sep 4, 2024
Decision date	Nov 5, 2024
Days to decision	62 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gri-Alleset, Inc.</b>
Location	Flowery Branch, GA, US
Contact	Marty Paugh
510(k) history	4 submissions · 4 cleared · 2021-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Resources Group, Inc.</b>
Contact	Julie Stephens

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242664/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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