

**K201876 Soteria Bed Barrier**Sep 1, 2022  
786 days to decisionK201876 · Product code: **QTV** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k201876/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mattress And Bed Deck Cover (medical Purposes) (QTV)
Date received	Jul 7, 2020
Decision date	Sep 1, 2022
Days to decision	786 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Trinity Guardion</b>
Location	Batesville, IN, US
Contact	Bruce Rippe
510(k) history	1 submissions · 1 cleared · 2022-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201876/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026