

**K222798 Rejoni Intrauterine Catheter**Dec 16, 2022  
91 days to decisionK222798 · Product code: **LKF** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k222798/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cannula, Manipulator/injector, Uterine (LKF)
Date received	Sep 16, 2022
Decision date	Dec 16, 2022
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Rejoni, Inc.</b>
Location	Bedford, MA, US
Contact	Brian Bergeron
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/k222798/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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