FDA 510(k) Premarket Notification

K222798 Rejoni Intrauterine Catheter

CLEARED

Dec 16, 2022
91 days to decision

K222798 · Product code: **LKF** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k222798/

SUBMISSION DETAILS

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

Company	**Rejoni, Inc.**
Location	Bedford, MA, US
Contact	Brian Bergeron
510(k) history	1 submissions · 1 cleared · 2022-2022