

**K223890 NAJA Gastrointestinal Catheter**Jun 16, 2023  
171 days to decisionK223890 · Product code: **FGD** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k223890/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention, Barium Enema With Bag (FGD)
Date received	Dec 27, 2022
Decision date	Jun 16, 2023
Days to decision	171 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Chess Medical, Inc.</b>
Location	Montreal, CA
Contact	Dr. Yen-I Chen
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Sloan Regulatory Consulting</b>
Contact	Christopher M. Sloan

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.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223890/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 27, 2026