FDA 510(k) Premarket Notification

K221952 Endoscope Model EG-580UT and Endoscope Model EG-580UR

CLEARED

Aug 4, 2022
30 days to decision

K221952 · Product code: **ODG** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k221952/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Endoscopic Ultrasound System, Gastroenterology-urology (ODG)
Date received	Jul 5, 2022
Decision date	Aug 4, 2022
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Fujifilm Corporation**
Location	Ashigara Kami-Gun, JP
Contact	Randy Vader
510(k) history	62 submissions · 62 cleared · 2018-2026

REGULATORY CONSULTANT

Consulting firm	**FUJIFILM Healthcare Americas Corporation**
Contact	Kotei Aoki

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k221952/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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