

K201861 Bio Fluff SystemMar 2, 2022
604 days to decisionK201861 · Product code: **KPL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k201861/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colonic Irrigation System (KPL)
Date received	Jul 6, 2020
Decision date	Mar 2, 2022
Days to decision	604 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gnali Bocia S.R.L.
Location	Lumezzane, IT
Contact	Katy Gnali
510(k) history	1 submissions · 1 cleared · 2022-2022

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