

K203633 Enteral Extension SetsAug 19, 2021
251 days to decisionK203633 · Product code: **PIF** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k203633/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastrointestinal Tubes With Enteral Specific Connectors (PIF)
Date received	Dec 11, 2020
Decision date	Aug 19, 2021
Days to decision	251 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	GBUK Group, Ltd.
Location	Selby, GB
Contact	Lucy Islip
510(k) history	2 submissions · 2 cleared · 2021-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203633/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026