

K072831 FROGDec 12, 2008
436 days to decisionK072831 · Product code: **FPD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k072831/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube, Feeding (FPD)
Date received	Oct 3, 2007
Decision date	Dec 12, 2008
Days to decision	436 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Newby-Coombs, LLC
Location	Branchville, NJ, US
Contact	KARLA COOMBS
510(k) history	1 submissions · 1 cleared · 2008-2008

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k072831/> 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 June 24, 2026