

K150711 Salem Sump Dual Lumen Stomach Tube with Multi-functional Port

Oct 8, 2015
203 days to decisionK150711 · Product code: **PIF** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k150711/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastrointestinal Tubes With Enteral Specific Connectors (PIF)
Date received	Mar 19, 2015
Decision date	Oct 8, 2015
Days to decision	203 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Covidien
Location	North Haven, CT, US
Contact	Jim Welsh
510(k) history	130 submissions · 126 cleared · 2008-2024

Covidien is an Irish-registered global healthcare products company headquartered in North Haven, Connecticut. Now part of Medtronic following a 2015 acquisition, the brand continues to operate as a major medical device manufacturer. Covidien maintains a strong FDA 510(k) regulatory record with cleared devices from total submissions spanning 2008 to 2024. The company specializes in General & Plastic Surgery devices, with a dominant focus on surgical staplers, sutures, and wound closure systems. Recent clearances include advanced stapling technologies, endotracheal tubes, a...

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