FDA 510(k) Premarket Notification

CLEARED

K072814 CONVENIENCE KIT FOR SINGLE-INCISION LAPAROSCOPIC SURGERY AND OTHER ADVANCED LAPAROSCOPIC PROCEDURES

Apr 16, 2008
198 days to decision

K072814 · Product code: **KDD** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k072814/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Surgical Instrument, Disposable (KDD)
Date received	Oct 1, 2007
Decision date	Apr 16, 2008
Days to decision	198 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Covidien**
Location	North Haven, CT, US
Contact	ROBERT ZOTT
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...