FDA 510(k) Premarket Notification

CLEARED

K162582 HumiGard Surgical Humidification System, HumiGard Humdified Insufflation Kit

Jun 23, 2017
281 days to decision

K162582 · Product code: **HIF** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k162582/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Laparoscopic (HIF)
Date received	Sep 15, 2016
Decision date	Jun 23, 2017
Days to decision	281 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Fisher & Paykel Healthcare**
Location	Auckland, NZ
Contact	Tina O'Brien
Website	http://www.fphcare.com/
510(k) history	5 submissions · 5 cleared · 2017-2024

Fisher & Paykel Healthcare is a global medical device manufacturer driving innovation in healthcare technologies for over 50 years. The company operates with a manufacturing facility in Auckland, New Zealand, and specializes in respiratory care, humidification systems, and therapeutic devices for hospital and home settings. The company has received FDA 510(k) clearances from total submissions since 2017. Anesthesiology devices represent the dominant category, accounting for approximately 80% of regulatory submissions. The latest clearance was received in 2024, demonstrati...