FDA 510(k) Premarket Notification

K120815 INNERSENSE ESOPHAGEAL TEMPERATURE/FEEDING TUBE

CLEARED

Mar 6, 2013
352 days to decision

K120815 · Product code: **FPD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k120815/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube, Feeding (FPD)
Date received	Mar 19, 2012
Decision date	Mar 6, 2013
Days to decision	352 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Philips Medical Systems**
Location	Seattle, WA, US
Contact	PETER SCHIPELLITI
510(k) history	107 submissions · 105 cleared · 2002-2021

Philips Medical Systems is a Dutch multinational health technology company headquartered in Amsterdam with U.S. operations based in Seattle. The company evolved from a consumer electronics conglomerate founded in 1891 to a healthcare-focused organization. Philips Medical Systems has received FDA 510(k) clearances from total submissions between 2002 and 2021. The company's regulatory focus centered on Cardiovascular devices, which represented 79% of all submissions. This historical record reflects the company's significant presence in diagnostic ultrasound systems and pati...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k120815/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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