FDA 510(k) Premarket Notification

K760453 REGULATOR, PRESSURE, CUFF

CLEARED

Sep 13, 1976
28 days to decision

K760453 · Product code: **JOH** · Anesthesiology
Source: https://www.510kdatabase.net/k760453/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube Tracheostomy And Tube Cuff (JOH)
Date received	Aug 16, 1976
Decision date	Sep 13, 1976
Days to decision	28 days
Third-party review	No

APPLICANT

Company	**Boehringer Laboratories**
Location	Mchenry, IL, US
Website	http://www.boehringerlabs.com
510(k) history	38 submissions · 38 cleared · 1976-2024

Boehringer Laboratories is a family-owned American medical technology company headquartered in Phoenixville, Pennsylvania, with operations in McHenry, US. The company specializes in respiratory therapy and minimally invasive surgical devices. Boehringer Laboratories has maintained a strong FDA 510(k) regulatory record since 1976. The company has received FDA 510(k) clearances from total submissions, with no denied submissions. Recent clearances span 2024, demonstrating continued active development. The company's portfolio focuses primarily on anesthesiology devices, inclu...