FDA 510(k) Premarket Notification

K013976 BOEHRINGER MRI SUCTION REGULATORY

CLEARED

Jan 8, 2002
36 days to decision

K013976 · Product code: **KDP** · General Hospital
Source: https://www.510kdatabase.net/k013976/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Regulator, Vacuum (KDP)
Date received	Dec 3, 2001
Decision date	Jan 8, 2002
Days to decision	36 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Boehringer Laboratories**
Location	Mchenry, IL, US
Contact	JOHN KARPOWICZ
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...