

K950397 SYSTEM 22 VALVEApr 14, 1995
72 days to decisionK950397 · Product code: **BYE** · Anesthesiology
Source: <https://www.510kdatabase.net/k950397/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Attachment, Breathing, Positive End Expiratory Pressure (BYE)
Date received	Feb 1, 1995
Decision date	Apr 14, 1995
Days to decision	72 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Turnkey Intergration USA, Inc.
Location	Indianapolis, IN, US
Contact	DOUGLAS W STUART
510(k) history	26 submissions · 23 cleared · 1990-1999

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