

K964961 MODEL 405T WITH ETCO2 OPTIONMay 14, 1997
154 days to decisionK964961 · Product code: **CCK** · Anesthesiology
Source: <https://www.510kdatabase.net/k964961/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Gas, Carbon-dioxide, Gaseous-phase (CCK)
Date received	Dec 11, 1996
Decision date	May 14, 1997
Days to decision	154 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Ivy Biomedical Systems, Inc.
Location	Branford, CT, US
Contact	DICK LISTRO
Website	https://ivybiomedical.com
510(k) history	27 submissions · 27 cleared · 1986-2024

Ivy Biomedical Systems, Inc. is a privately-held medical device company headquartered in Branford, Connecticut. The company is the market leader for precision cardiac gating monitors used for synchronization of radiographic image acquisition across major imaging modalities including nuclear medicine, computed tomography, magnetic resonance, positron emission tomography, and single photon emission computed tomography. The company has received FDA 510(k) clearances from total submissions since its first clearance in 1986. Cardiovascular devices represent the dominant focus,...
