

K002846 HEADSTAR'S MANUAL EMERGENCY RESUSCITATOR

Jun 6, 2001
267 days to decision

K002846 · Product code: **BTM** · Anesthesiology
Source: <https://www.510kdatabase.net/k002846/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Emergency, Manual (resuscitator) (BTM)
Date received	Sep 12, 2000
Decision date	Jun 6, 2001
Days to decision	267 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Headstar Medical Products Co., Ltd.
Location	Taipei Hsien, CN
510(k) history	2 submissions · 2 cleared · 2001-2013

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k002846/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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