

**K042556 SHINEBALL PVC MANUAL RESUSCIATOR, ENT-1001,
ENT-1003, ENT-1005, SHINEBALL SILICONE MANUAL
RESUSCIATOR, ENT-1022,**

Mar 11, 2005
172 days to decision

K042556 · Product code: **BTM** · Anesthesiology
Source: <https://www.510kdatabase.net/k042556/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Emergency, Manual (resuscitator) (BTM)
Date received	Sep 20, 2004
Decision date	Mar 11, 2005
Days to decision	172 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Enter Medical Corporation
Location	Gui Shan Xiang, Tao Yuan Hsien, TW
Contact	TZONG-FUH KUO
510(k) history	1 submissions · 1 cleared · 2005-2005

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k042556/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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