

K122610 PLAXTRON CPAP SYSTEM, MODEL CH-FFM-87XX/CH-FFM-88XX SERIESAug 5, 2013
343 days to decisionK122610 · Product code: **BYE** · Anesthesiology
Source: <https://www.510kdatabase.net/k122610/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Attachment, Breathing, Positive End Expiratory Pressure (BYE)
Date received	Aug 27, 2012
Decision date	Aug 5, 2013
Days to decision	343 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sen MU Technology Co., Ltd.
Location	Kaohsiung City, TW
Contact	MING-YIE JN, PH.D.
510(k) history	1 submissions · 1 cleared · 2013-2013

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