

K080661 MODELS TENS 7000, EMS 7500 AND TWIN STIMMar 24, 2008
14 days to decisionK080661 · Product code: **IPF** · Physical MedicineSource: <https://www.510kdatabase.net/k080661/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered (IPF)
Date received	Mar 10, 2008
Decision date	Mar 24, 2008
Days to decision	14 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Koalaty Products, Inc.
Location	Tampa, FL, US
Contact	JAY MANSOUR
510(k) history	3 submissions · 3 cleared · 2007-2010

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