

K101273 DYNAMIC ECG SYSTEM MODEL TLC5000Sep 30, 2011
512 days to decisionK101273 · Product code: **MLO** · Cardiovascular
Source: <https://www.510kdatabase.net/k101273/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph, Ambulatory, With Analysis Algorithm (MLO)
Date received	May 6, 2010
Decision date	Sep 30, 2011
Days to decision	512 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Contec Medical System Co., Ltd.
Location	Zhong Shan, Shanghai, CN
Contact	Diana Hong
510(k) history	12 submissions · 12 cleared · 2008-2019

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