

K060627 TAG-IT CYSTIC FIBROSIS KITJun 7, 2006
90 days to decisionK060627 · Product code: **NUA** · Pathology
Source: <https://www.510kdatabase.net/k060627/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Cystic Fibrosis Transmembrane Conductance Regulator, Gene Mutation Detection (NUA)
Date received	Mar 9, 2006
Decision date	Jun 7, 2006
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Tm Bioscience Corporation
Location	Toronto, Ontario, CA
Contact	NANCY KRUNIC
510(k) history	2 submissions · 1 cleared · 2005-2006

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