

**K000884 BD PROBETEC ET MYCOBACTERIUM
TUBERCULOSIS COMPLEX (CTB) CULTURE IDENTIFICATION
ASSAY**Jan 19, 2001
305 days to decisionK000884 · Product code: **NDZ** · Microbiology
Source: <https://www.510kdatabase.net/k000884/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Nucleic Acid Amplification, Growth Identification, Mycobacterium Tuberculosis (NDZ)
Date received	Mar 20, 2000
Decision date	Jan 19, 2001
Days to decision	305 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Becton Dickinson Biosciences
Location	Sparks, MD, US
Contact	COLLEEN ROHRBECK
510(k) history	1 submissions · 1 cleared · 2001-2001

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