FDA 510(k) Premarket Notification

K151589 BD MAX CT/GC/TV, BD MAX INSTRUMENT

CLEARED

Sep 6, 2016
452 days to decision

K151589 · Product code: **OUY** · Microbiology
Source: https://www.510kdatabase.net/k151589/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Trichomonas Vaginalis Nucleic Acid Amplification Test System (OUY)
Date received	Jun 12, 2015
Decision date	Sep 6, 2016
Days to decision	452 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Becton, Dickinson and Company**
Location	Franklin Lakes, NJ, US
Contact	KATIE COYLE
Website	https://www.bd.com
510(k) history	134 submissions · 134 cleared · 2010-2026

Becton, Dickinson and Company is an American multinational medical technology company headquartered in Franklin Lakes, New Jersey. BD manufactures and sells medical devices, instrument systems, and reagents globally. The company maintains a strong FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions spanning 2010 to 2026. BD's cleared devices span multiple categories including microbiology systems, blood collection products, and general hospital devices. The company's latest clearance in 2026 reflects continued innovation and regulatory engagemen...