

K003380 BIOTEQUE VAGINAL DILATORJan 29, 2001
90 days to decisionK003380 · Product code: **HDX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k003380/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vaginal (HDX)
Date received	Oct 31, 2000
Decision date	Jan 29, 2001
Days to decision	90 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Bioteque America, Inc.
Location	Levittown, PA, US
Contact	DENIS DORSEY
510(k) history	10 submissions · 10 cleared · 1992-2004

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