

K150932 Sheath IntroducerJul 22, 2016
473 days to decisionK150932 · Product code: **DRE** · Cardiovascular
Source: <https://www.510kdatabase.net/k150932/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Apr 6, 2015
Decision date	Jul 22, 2016
Days to decision	473 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bioteque Corp.
Location	Levittown, PA, US
Contact	Simon Lin
510(k) history	11 submissions · 10 cleared · 1992-2016

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