FDA 510(k) Premarket Notification

K101832 BIOPINCE ULTRA FULL CORE BIOPSY INSTRUMENT

CLEARED

Aug 27, 2010
57 days to decision

K101832 · Product code: **KNW** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k101832/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Jul 1, 2010
Decision date	Aug 27, 2010
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medical Device Technologies, Inc.**
Location	Gainsville, FL, US
Contact	TRUDY D ESTRIDGE
510(k) history	46 submissions · 46 cleared · 1992-2010