FDA 510(k) Premarket Notification

K042290 VACUUM ASSISTED CORE BIOPSY DEVICE

CLEARED

Oct 6, 2004
43 days to decision

K042290 · Product code: **KNW** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k042290/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Aug 24, 2004
Decision date	Oct 6, 2004
Days to decision	43 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Suros Surgical Systems, Inc.**
Location	Indianapolis, IN, US
Contact	JOSEPH MARK
510(k) history	3 submissions · 3 cleared · 2004-2007