FDA 510(k) Premarket Notification

K142125 New Medax Biopsy Systems

CLEARED

Dec 22, 2015
505 days to decision

K142125 · Product code: **KNW** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k142125/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Aug 4, 2014
Decision date	Dec 22, 2015
Days to decision	505 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Medax Srl Unipersonale**
Location	Poggio Rusco, IT
Contact	Stefano Cavalieri
510(k) history	5 submissions · 5 cleared · 2015-2020