FDA 510(k) Premarket Notification

CLEARED

K172558 iVAS 8g Bone Biopsy Kit, iVAS 11g Bone Biopsy Kit, iVAS 10g Bone Biopsy Kit

Oct 5, 2017
42 days to decision

K172558 · Product code: **KNW** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k172558/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Aug 24, 2017
Decision date	Oct 5, 2017
Days to decision	42 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker Corporation**
Location	Malwah, NJ, US
Contact	Kristi Ashton
Website	http://www.stryker.com/
510(k) history	81 submissions · 81 cleared · 2010-2023

Stryker Corporation is an American multinational medical technology company headquartered in Portage, Michigan. The company develops and markets surgical equipment, neurotechnology, orthopedic implants, and patient safety systems used globally across medical specialties. Stryker has received FDA 510(k) clearances from total submissions between 2010 and 2023. The company's cleared devices span orthopedic surgery, neurosurgery, general and plastic surgery, and ear, nose, and throat specialties. This regulatory record reflects the company's broad portfolio across surgical an...