FDA 510(k) Premarket Notification

CLEARED

K180327 Stryker iVAS 13g Bone Biopsy Kit

Feb 26, 2018
20 days to decision

K180327 · Product code: **KNW** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k180327/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Instrument, Biopsy (KNW)
Date received	Feb 6, 2018
Decision date	Feb 26, 2018
Days to decision	20 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...