

K130430 IVAS 10MM AND 15MM BALLOON CATHETERMay 23, 2013
92 days to decisionK130430 · Product code: **HRX** · Orthopedic
Source: <https://www.510kdatabase.net/k130430/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Arthroscope (HRX) |
| Date received | Feb 20, 2013 |
| Decision date | May 23, 2013 |
| Days to decision | 92 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Stryker Corporation |
| Location | Malwah, NJ, US |
| Contact | CHRISTINA MCKEE |
| 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...
