FDA 510(k) Premarket Notification

# K202619 KardiFlex PTCA Balloon Dilatation Catheter

**CLEARED**

Apr 29, 2021
231 days to decision

K202619 · Product code: **LOX** · Cardiovascular
Source: https://www.510kdatabase.net/k202619/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX) |
| Date received | Sep 10, 2020 |
| Decision date | Apr 29, 2021 |
| Days to decision | 231 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Medcaptain Life Science Co., Ltd.** |
| Location | Shenzhen, CN |
| Contact | David Xia |
| 510(k) history | 5 submissions · 5 cleared · 2021-2023 |