**CLEARED**

Aug 19, 2022
57 days to decision

# K221824 OpClear Platform (CU3 DI3), OpClear Control Unit with Footswitch (CS-CU33), OpClear Disposable Procedure Kits (CS-10-00-300, CS-10-30-300, CS-10-00-315, CS-10-30-315, CS-10-00-330, CS-10-30-330, CS-05-00-290, CS-05-30-290), Contd from 3 above: CS-05-00-300, CS-05-30-300, CS-05-00-315, CS-05-30-315

K221824 · Product code: **OCX** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k221824/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Endoscopic Irrigation/suction System (OCX) |
| Date received | Jun 23, 2022 |
| Decision date | Aug 19, 2022 |
| Days to decision | 57 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Cipher Surgical Limited** |
| Location | Coventry, GB |
| Contact | Justin Buch |
| 510(k) history | 1 submissions · 1 cleared · 2022-2022 |