

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

Aug 19, 2022
57 days to decision

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

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Device record: <https://www.510kdatabase.net/k221824/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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