

K213271 Mediclose™ SystemAug 31, 2023
700 days to decisionK213271 · Product code: **OCW** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k213271/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Tissue Approximation Device (OCW)
Date received	Sep 30, 2021
Decision date	Aug 31, 2023
Days to decision	700 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Health Value Creation B.V., Trading AS Corporis Medical
Location	Maastricht, NL
Contact	Kim Sondeijker
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Donawa Lifescience Consulting Srl
Contact	Roger Gray

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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