

K232917 Chemo MouthpieceJan 23, 2024
126 days to decisionK232917 · Product code: **QUA** · Dental
Source: <https://www.510kdatabase.net/k232917/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intraoral Cooling Device (QUA)
Date received	Sep 19, 2023
Decision date	Jan 23, 2024
Days to decision	126 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Chemo Mouthpiece, LLC
Location	Closter, NJ, US
Contact	David Yoskowitz
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	MCRA
Contact	Devjani Saha

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

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