

K230825 Smileyscope System (Therapy Mode)Sep 25, 2023
185 days to decisionK230825 · Product code: **QRA** · Physical MedicineSource: <https://www.510kdatabase.net/k230825/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Virtual Reality Behavioral Therapy Device For Pain Relief (QRA)
Date received	Mar 24, 2023
Decision date	Sep 25, 2023
Days to decision	185 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Smileyscope Holding, Inc.
Location	Austin, TX, US
Contact	Paul Leong
510(k) history	1 submissions · 1 cleared · 2023-2023

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