September 25, 2023

Smileyscope Holding Inc.
Dr. Paul Leong
Chief Medical Officer
701 Tillery Street #12
Austin, Texas 78702

Re: K230825
Trade/Device Name: Smileyscope System (Therapy Mode)
Regulation Number: 21 CFR 890.5800
Regulation Name: Virtual reality behavioral therapy device for pain relief
Regulatory Class: Class II
Product Code: QRA
Dated: August 28, 2023
Received: August 29, 2023

Dear Dr. Paul Leong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Amber T. Ballard -S

Amber Ballard, PhD
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230825

Device Name
Smileyscope System (Therapy Mode)

Indications for Use *(Describe)*
The Smileyscope System's Therapy Mode is a prescription-use immersive virtual reality system intended to provide adjunctive treatment based on guided relaxation and other evidence-based behavioral methods for patients aged 4-11 years who can cooperate and interact with the device at a developmentally appropriate level. The Smileyscope Therapy Mode is intended to temporarily reduce and/or manage pain and temporarily relieve acute procedural anxiety associated with needle procedures (e.g., venipuncture, IV placement, vaccination, port access, subcutaneous injections). The device is not intended to treat anxiety disorders or specific phobias (e.g. trypanophobia).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Device Trade Name:	Smileyscope System (Therapy Mode)
Device Model:	SSVR US
Common Name:	Virtual Reality Behavioral Therapy Device
510(k) Number:	K230825
Manufacturer:	Smileyscope Pty Ltd 1/333 Exhibition St Melbourne VIC 3000 Australia
Sponsor:	Smileyscope Holding Inc 701 Tillery Street #12 Austin, TX 78702
Contact:	Paul Leong Chief Medical Officer +1 888 300 7117
Prepared by:	MCRA, LLC 803 7th St NW Washington, DC 20001 Office: 202.552.5800
Date Prepared:	September 21, 2023
Classification:	21 CFR 890.5800 (Virtual Reality Behavioral Therapy Device For Pain Relief)
Class:	II
Product Codes:	QRA
Predicate Device:	EaseVRx (AppliedVR Inc), DEN210014

Device Description:

Smileyscope is an immersive virtual reality (VR) device, consisting of Hardware and Software components. In Smileyscope Therapy mode, the device delivers 3-dimensional virtual reality treatment based on guided relaxation and other evidence-based behavioral methods to temporarily reduce pain and temporarily relieve acute procedural anxiety in individuals undergoing needle procedures. This prescription-use device uses pre-loaded software on a proprietary hardware and software platform to deliver treatment. The Smileyscope device is supplied with a USB charger and USB cable to facilitate charging.

Hardware:

The physical device consists of two major subcomponents (Figure 1 and Figure 2).

First, a detachable mobile interface, or "Faceplate", that clinicians can interact with via a touchscreen. The Faceplate contains an embedded mobile phone (Google Pixel 3) running Smileyscope software. Second, a head-mounted virtual reality headset, or "Main Body". The Main Body is placed on the patient's head and positioned via the Adjustable Head Strap. The Faceplate attaches to the Main Body via magnets (Figure 2, final step in **Table 1**). Lenses in the Main Body permit the display of virtual reality.

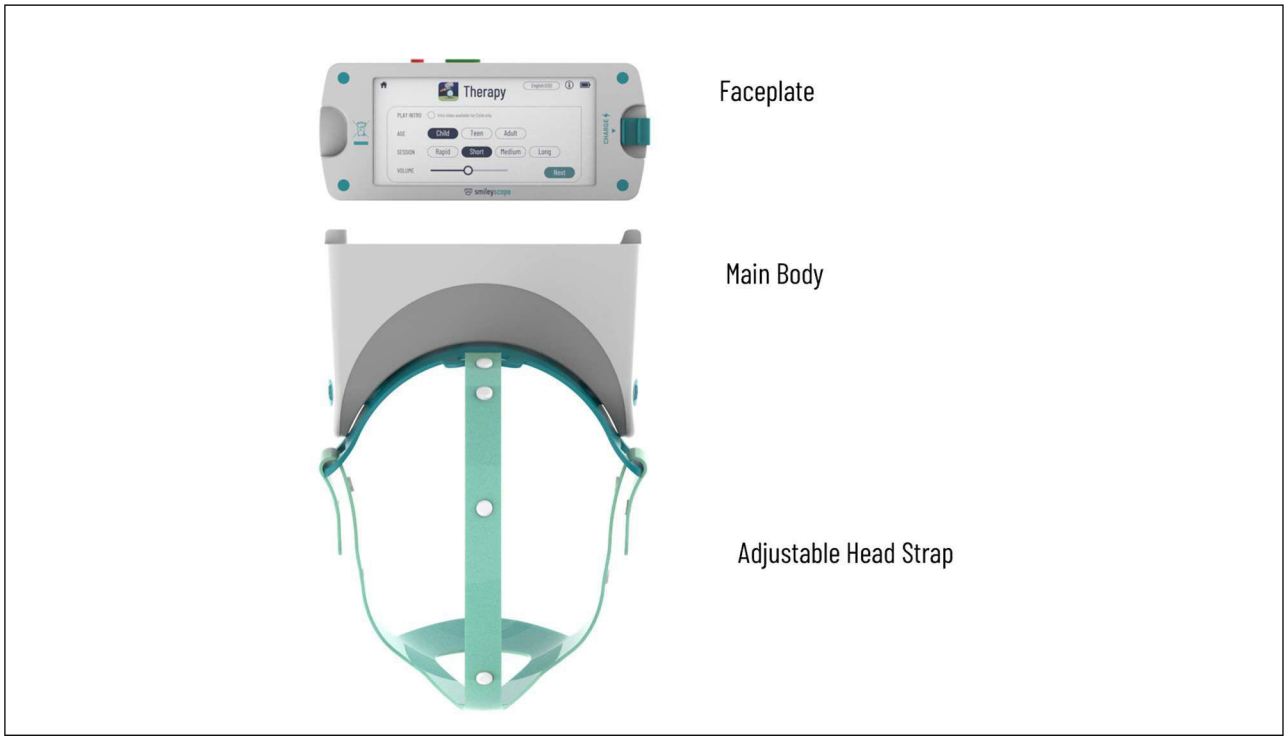


Figure 1: Smileyscope System, components labelled.

Figure 2: Smileyscope System, Front View, with Frontplate Attached to Main Body.

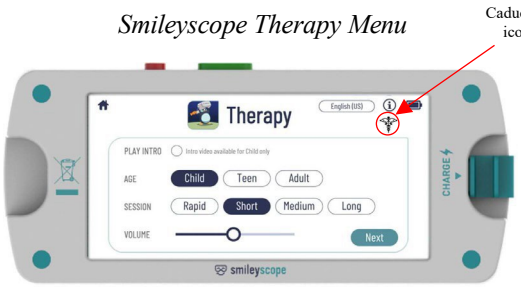
Software:
Clinicians use the Smileyscope System to administer the Smileyscope Therapy mode. In this software mode, the Smileyscope System provides evidence-based virtual reality behavioral therapy during a needle procedure.

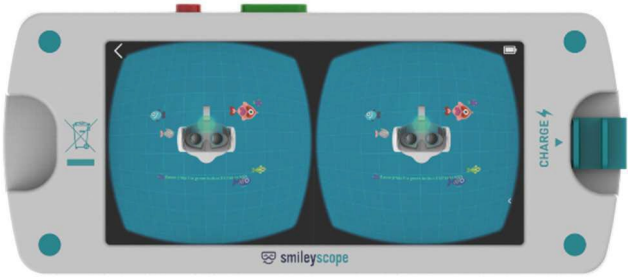
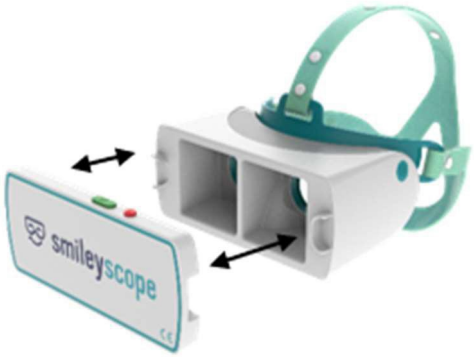
While the patient undergoes the needle procedure in the real world, the Smileyscope Therapy Mode provides an interactive "underwater adventure" virtual reality experience. The virtual reality experience contains evidence-based guided relaxation and behavioral techniques designed to temporarily reduce pain and temporarily relieve acute procedural anxiety during needle procedures.

The underwater adventure can be configured by the Clinician to last 1-10 minutes. Audio cues are provided throughout the virtual reality experience which allow the clinician to synchronize the procedure with common needle-based procedures. However, precise timing is not necessary. The experience loops if the procedure takes longer than anticipated. The workflow is elaborated in **Table 1**.

The software has been designed to avoid common adverse effects associated with virtual reality. For example it contains minimal motion (to reduce motion sickness) and objects are positioned at optimal distances in the virtual environment so as to avoid virtual reality disequilibrium.

Table 1: Smileyscope Therapy Mode Workflow

Clinician Interface	Description
Home Screen 	The clinician turns on the device by depressing the red button. The software automatically loads the Home Screen. After accepting the user agreement popup, the clinician is presented with the screen depicted on the left hand side. The clinician interacts with the touchscreen and loads the needle therapy program by pressing the 'Get Started' button in the bottom right. Note that only the Smileyscope Therapy mode is intended for therapeutic use and the subject of K230825. The remaining modes fall outside the scope of K230825.
Smileyscope Therapy Menu 	The clinician is presented the Smileyscope Therapy Menu. Smileyscope Therapy mode is visually designated by the Cadeuceus icon at top right. The Indications for Use are displayed in a popup when the Caduceus is clicked. This screen allows clinician to select the audio track for the intended age range. There is a brief optional introductory animated video which informs the patient about what might happen in a needle procedure. The clinician can also select the duration of the virtual reality experience, and control the audio volume. They press "Next" to proceed to the Body Part Selection screen.
Body Part Selection 	In the Body Part Selection Screen. In this screen the Clinician can select the procedure site, which determines where the virtual fish will nibble during the virtual reality experience.

Calibration Screen  *Faceplate Attaches to Main Body*  	Once a site has been selected, Smileyscope Therapy mode engages virtual reality and displays two images, one for each eye. This is the Calibration Screen. The Clinician places the Main Body on the patient, and attaches the Faceplate to the Main Body. This enables the virtual reality environment to be displayed via lenses in the Main Body. When the physical green button on the Faceplate is depressed three times, the unit orients the virtual world so it is displayed in front of the patient, and the experience begins. The experience will calibrate in any position (e.g. sitting or lying) in accordance with the Clinician's procedural workflow.
Underwater Adventure: Virtual Reality View 	The Virtual Reality Experience begins. The underwater adventure is displayed. The sequence begins with relaxation deep breathing, and progresses to an underwater sequence where choreographed to mimic the real-world needle experience. Threatening real-world stimuli (e.g., tourniquet) are reframed as less threatening stimuli (e.g. diving band), and the needle is mimicked by virtual fish. The user can interact with virtual fish through gaze-based interaction. Audio plays so the clinician is aware of the patient's progress through the adventure. Once the virtual reality experience concludes, the experience loops and the user can start the experience again.

Indications For Use:

The Smileyscope System's Therapy Mode is a prescription-use immersive virtual reality system intended to provide adjunctive treatment based on guided relaxation and other evidence-based behavioral methods for patients aged 4-11 years who can cooperate and interact with the device at a developmentally appropriate level. The Smileyscope Therapy Mode is intended to temporarily reduce and/or manage pain and temporarily relieve acute procedural anxiety associated with needle procedures (e.g., venipuncture, IV placement, vaccination, port access, subcutaneous injections). The device is not intended to treat anxiety disorders or specific phobias (e.g. trypanophobia).

Comparison of Technological Characteristics With The Predicate Device and Substantial Equivalence:

Table 2: Summary of Substantial Equivalence Criteria, Primary Predicate, and Smileyscope System (Therapy Mode)

Substantial Equivalence Criteria	**Primary Predicate** **EaseVRx, AppliedVR Inc**	**Subject Device** **Smileyscope System (Therapy Mode) Smileyscope Holding Inc**	**Comparison**
Indication for Use	EaseVRx is a prescription-use immersive virtual reality system intended to provide adjunctive treatment based on cognitive behavioral therapy skills and other evidence-based behavioral methods for patients (age 18 and older) with a diagnosis of chronic lower back- pain (defined as moderate to severe pain lasting longer than three months). The device is intended for in-home use for the	The Smileyscope System's Therapy Mode is a prescription-use immersive virtual reality system intended to provide adjunctive treatment based on guided relaxation and other evidence-based behavioral methods for patients aged 4-11 years. The Smileyscope Therapy Mode is intended to temporarily reduce and/or manage pain and temporarily relieve acute procedural anxiety associated with needle procedures	Smileyscope is used in a pediatric population, while EaseVRx is used in an adult population

	reduction of pain and pain interference associated with chronic lower back pain.	(e.g., venipuncture, IV placement, vaccination, port access, subcutaneous injections). The device is not intended to treat anxiety disorders or specific phobias (e.g. trypanophobia).	
Intended Use	The device is intended for in-home use for the reduction of pain and pain interference associated with chronic lower back pain.	The Therapy Mode is intended to temporarily reduce and/or manage pain and temporarily relieve acute procedural anxiety associated with needle procedures	Both are intended to reduce pain
Clinical or scientific data that demonstrates that the device safe and effective, and does not raise different questions of safety and effectiveness compared to the predicate device.	Clinical and scientific data: randomized controlled study demonstrating safety and efficacy. (n=188) Randomized, multi-arm, "blinded" study with concurrent sham control. Location of Study not publicly available in Decision Summary.	Clinical and scientific data: two randomized controlled studies demonstrating safety and efficacy. (combined n=254) Randomized, multi-arm, "blinded" study with concurrent ("active") control. Outside of United States only.	Both have RCTs with a large patient population showing effectiveness and safety.

Table 3. Comparison of Technical Characteristics

Substantial Equivalence Criteria	**Primary Predicate** **EaseVRx, AppliedVR Inc**	**Subject Device** **Smileyscope Therapy Smileyscope Holding Inc**	**Comparison**
Headset Manufacturer and Model #	GoerTek Technology Inc. Model: A 7510/Pico G2 4K	Smileyscope Hardware Model: SSVR US	-
Rating	5V DC, 2A	5V DC/3A or 9V/2A	Similar

Weight	278 (w/o Band), 470 (total)	530 grams	Similar, low risk characteristic

Framerate in virtual reality (frame per second)	72 fps	60 fps	Similar
Screen Resolution	3840 X 2160	2160x1080 pixels	Similar, low risk characteristic
Number of pixels horizontally and vertically per eye	Horizontally: 1907 Vertically: 1964	Horizontally: 1072 Vertically: 1072	Similar, low risk characteristic
Luminance	Maximum: 0.06 nits Minimum: 63.4 nits	2.4 to 426 nits	Similar[1]
Interpupillary distance (IPD) and IPD range of the headset	Default 63mm, optical adaptive range is from 55~7l mm	64mm, approximately 55-70mm usable range	Same
Tracking degrees of headset x/y/z 360º	3 degrees of freedom	3 degrees of freedom	Same
Eye relief for prescription lenses	17mm	16mm	Same
Field of view per eye	Horizontally: 98 Vertically: 101	Horizontal: 90 degrees Vertical: 90 degrees	Similar
Range in depths of the virtual content in the software	2m for optics; 3m for launcher software	0.5m to infinity depending on object (arms at ~0.5m, horizon at infinity)	Similar, not clinically relevant

Table 4. Comparison of Device Risks

Primary Predicate: Identified Risk to Health	**Smileyscope Therapy: Mitigation Measure**
Adverse tissue reaction	Biocompatibility evaluation Labeling
Electric shock or burn or interference with other devices	Electromagnetic compatibility (EMC) testing Electrical, mechanical, and thermal safety testing
Nausea and motion sickness	Clinical performance testing Labeling
Discomfort	Clinical performance testing Labeling

Ineffective treatment	Clinical performance testing Software verification, validation, and hazard analysis Labeling

Use error or improper device use leading to a delay in treatment	Labeling

[1] Nathan Matsuda et al., "Realistic Luminance in VR," in *SIGGRAPH Asia 2022 Conference Papers* (SA '22: SIGGRAPH Asia 2022, Daegu Republic of Korea: ACM, 2022), 1–8, https://doi.org/10.1145/3550469.3555427.

Special Controls were applied to the Primary Predicate. Smileyscope submits that these Special Controls have been met by Smileyscope Therapy Mode.

Table 5: Special Controls applied from the Primary Predicate

Special Control from Primary Predicate
(1) Clinical performance testing under the labeled conditions for use must validate the model of behavioral therapy as implemented by the device and evaluate all adverse events.
(2) The patient-contacting components of the device must be demonstrated to be biocompatible.
(3) Software verification, validation, and hazard analysis must be performed.
(4) Electromagnetic compatibility and electrical, mechanical, and thermal safety testing must be performed.
(5) Labeling must include the following: (i) A warning regarding the risk of nausea and motion sickness
(ii) A warning regarding the risk of discomfort from the device
(iii) A summary of the clinical testing with the device

Performance Testing Summary:

The Smileyscope has undergone performance testing in line with FDA guidance documents, commensurate with the Predicate Device.

Hardware

Smileyscope's hardware has undergone performance testing. A summary is presented below.

Table 6: Technical specifications

Headset	Smileyscope Hardware
Rating	5V DC/3A or 9V/2A
Weight	530 grams
Framerate in virtual reality	60 frames per second (fps)
Screen Resolution	2160x1080 pixels
Horizontal and Vertical pixels per eye	1072 x 1072 (horizontal x vertical) pixels per eye
Luminance	2.4 to 426 nits
Interpupillary distance and range	64mm, approximately 55-70mm usable range
Tracking degrees of headset x/y/z 360 degrees	3 degrees of freedom
Eye relief for prescription lenses	16mm
Field of view per eye	90 degrees 90 degrees

Biocompatibility
The physical device is constructed of materials found in the Primary Predicate and FDA cleared products (e.g. PC/ABS, silicone etc.). The patient contacting components have undergone Biocompatibility Evaluation per FDA guidance "Use of International Standard ISO 10993-1:2018, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" (September 4, 2020). The patient contacting components are categorized as surface contacting with limited contact duration (less than 24 hours) of intact skin. Assessment of the device included the following tests according to the contact classification and duration of the patient-contacting materials:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization Test (ISO 10993-10:2010)
- Intracutaneous Reactivity (ISO 10993-10:2010)

Electrical Safety and Electromagnetic Capability
The embedded mobile phone hardware has undergone electromagnetic compatibility and electrical, mechanical, and thermal safety testing and declared conformance to the following harmonized standards and normative documents:

Electrical Safety:

- IEC 60950-1:2005 + A1:2009 + A2:2013
- EN 60950-1:2006 + A11:2009 + A1:2010 + A12:2011 + A2:2013
- IEC 62368-1:2014, EN 62368-1:2014 + A11:2017
- EN 62311:2008, EN 62479:2010
- EN 50360:2017, EN 62209-1:2016
- EN 50566:2017, EN 62209-2:2010

Electromagnetic Compatibility:

- Draft EN 301 489-1 v2.2.0
- Final Draft EN 301 489-3 V2.1.1
- Draft EN 301 489-17 V3.2.0
- Draft EN 301 489-19 V2.1.0
- Draft EN 301 489-52 V1.1.0
- EN 55032:2015/AC:2016 Class B
- EN 55035:2017

Software
The sponsor provided documentation for software with a "Minor" Level of Concern (LoC), as described in the FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." issued May 11, 2005. Documentation describing the software, software requirements specification, traceability, revision level history, verification, validation, hazard analysis and cybersecurity provides the foundation that the software will operate in a manner as described in the specifications.

Clinical Performance Testing

Smileyscope Therapy Mode has undergone Clinical Performance Testing. Smileyscope Therapy Mode was tested in two independent randomized clinical studies, which have been peer-reviewed and published in the *Journal of Pediatrics*[2]. Briefly, in both studies Smileyscope Therapy Mode, consistently demonstrated benefits for the primary endpoint of child-rated pain, and substantially reduced the secondary endpoint of procedural anxiety. The pre-specified primary safety and effectiveness endpoints were met in both studies, which were conducted outside of the United States only, in comparable population(s). These are summarized in Table 3 below. Overall, Smileyscope Therapy Mode was safe, with no significant adverse effects, specifically with regards to the Identified Risks to Health from the Primary Predicate's Special Controls. Adverse effects were mild (nausea, dizziness, headache, vomiting) and were self-limiting; they did not require pharmacotherapy.

Table 7: Summary of Smileyscope Therapy Mode Clinical Performance Testing

Stage	**Smileyscope Therapy Mode Total**	**Control Arm Total**	**Total**
Emergency Department study			
Enrollment	64	59	123
Treatment	64	59	123
Primary Safety Endpoint	Nil adverse effects	4 mild adverse effects	
Primary Effectiveness Endpoint: Change in Child Self-Rated Pain (Faces Pain Scale-Revised)	-1.39	+0.39	
Between-Group Difference	-1.78 units pain reduction with Smileyscope Therapy Mode (95% CI, -3.24 to -0.32) p=0.018		
Outpatient Pathology study			
Enrollment	63	68	131
Treatment	63	66	129
Primary Safety Endpoint	3 mild adverse effects	3 mild adverse effects	
Primary Effectiveness Endpoint: Change in Child Self-Rated Pain (Faces Pain Scale-Revised)	+1.37	+2.76	
Between-Group Difference	-1.39 units pain reduction with Smileyscope Therapy Mode (95% CI, -2.68 to -0.11) p=0.034		

[2] Evelyn Chan et al., "Virtual Reality for Pediatric Needle Procedural Pain: Two Randomized Clinical Trials," *The Journal of Pediatrics* 209 (April 29, 2019): 160–67, https://doi.org/10.1016/j.jpeds.2019.02.03

Conclusion:

Smileyscope Therapy Mode and the predicate device have the same intended use, have different technological characteristics, with appropriate clinical and scientific data that demonstrates the device is as safe and effective as a legally marketed device, and there are no different questions of safety and effectiveness than the predicate. The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as the Primary Predicate Device.