May 15, 2023

MMJ Labs, LLC
% Amy Baxter, MD
CEO
Pain Care Labs a dba of MML Labs, LLC
195 Arizona Ave LW08
Atlanta, GA 30307

Re: K202993
Trade/Device Name: Buzzy® (models: Mini Healthcare, XL Healthcare, Mini Personal, XL Personal, Pro); VibraCool® (models: Easy Fit, Extended, Plantar, Flex, Pro Healthcare, Pro Upper Extremity (UE), Pro Lower Extremity (LE), Pro Durable Medical Equipment (DME))

Regulation Number: 21 CFR 890.5975
Regulation Name: Therapeutic Vibrator
Regulatory Class: Class I
Product Code: PHW, IME
Dated: March 1, 2023
Received: March 2, 2023

Dear Dr. Baxter:

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, Ph.D.
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
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and Physical Medicine Devices
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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)*
K202993

Device Name
Buzzy® (models: Mini Healthcare, XL Healthcare, Mini Personal, XL Personal, Pro)
VibraCool® (models: Easy Fit, Extended, Plantar, Flex, Pro Healthcare, Pro Upper Extremity (UE), Pro Lower Extremity (LE), Pro Durable Medical Equipment (DME))

Indications for Use *(Describe)*
Buzzy® is intended to control pain associated with needle procedures (e.g., injections, vascular access, cannulation, lab draws, blood donation, dialysis, cosmetic and dental injections) and the temporary relief of minor injuries (muscle or tendon aches, splinters, and bee stings).

VibraCool® is intended for the temporary relief of minor injuries (muscle or tendon aches) and the treatment of myofascial pain post-surgery. It is also indicated for use prior to or during physical therapy to treat myofascial pain caused by trigger points, restricted motion and muscle tension.

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
K202993

DATE PREPARED
May 15, 2023

MANUFACTURER AND 510(k) OWNER
MMJ Labs, LLC
195 Arizona Avenue, LW08
Atlanta, GA 30307, USA
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Official Contact: Amy Baxter, MD, CEO

REPRESENTATIVE/CONSULTANT
Amy Baxter, MD

DEVICE INFORMATION

Proprietary Names/Trade Names:	Buzzy® (models: Mini Healthcare, XL Healthcare, Mini Personal, XL Personal, Pro), VibraCool® (models: Easy Fit, Extended, Plantar, Flex, Pro Healthcare, Pro Upper Extremity (UE), Pro Lower Extremity (LE), Pro Durable Medical Equipment (DME))
Primary Regulation:	Classification name: Therapeutic vibrator (21 CFR 890.5975, Product Code: PHW [Cold pack and vibrating massager], Class I / 510(k) Exempt)
Secondary Regulation:	Classification name: Cold pack (21 CFR 890.5700, Product Code: IME [Pack, hot or cold, reusable], Class I / 510(k) Exempt)

PREDICATE DEVICE IDENTIFICATION

510(k) Number	*Predicate Device Trade Name*	*Manufacturer*
K130631	Buzzy®	MMJ Labs, LLC

DEVICE DESCRIPTION

Buzzy® and VibraCool® devices are external use, skin contacting vibration devices that can be used with heat (for VibralCool® Flex, VibraCool® Pro UE and VibraCool® Pro LE)or cold therapy (for all Buzzy® and VibraCool® models) to provide pain relief. The brand names encompass the same two shapes of vibrating devices using the same motor. Buzzy Pro and VibraCool Pro are a new shape with the same motor submitted in this 510K. To accommodate various uses and anatomical locations, the Buzzy and VibraCool devices are available in three different shapes and are provided with different sets of accessories.

INDICATIONS FOR USE

Buzzy:

> Buzzy® is intended to control pain associated with needle procedures (e.g., injections, vascular access, cannulation, lab draws, blood donation, dialysis, cosmetic and dental injections) and the temporary relief of minor injuries (muscle or tendon aches, splinters, and bee stings).

VibraCool:

> VibraCool® is intended for the temporary relief of minor injuries (muscle or tendon aches) and the treatment of myofascial pain post-surgery. It is also indicated for use prior to or during physical therapy to treat myofascial pain caused by trigger points, restricted motion and muscle tension.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

MMJ Labs believes that the Buzzy and VibraCool are substantially equivalent to the predicate device based on the information summarized in Tables 1-3 below.

The subject devices have similar or identical design and dimensions, identical mechanism of action, similar or identical vibration settings, and use similar or identical materials to the original Buzzy devices cleared in K130631. The main differences between the subject and predicate devices are:

- the addition of the VibraCool accessories,
- the optional addition of heat therapy mode with VibraCool Flex, VibraCool Pro Upper, and VibraCool Lower Extremity,
- the added “Pro” lines of Buzzy and VibraCool, and
- updated indications for use.

Table 1. Comparison of the subject (Buzzy®) and predicate (Buzzy®) devices									
	Predicate Device (K130631) – Buzzy®				Subject Device (K202993) – Buzzy®				
Model Names	**Buzzy® Mini Healthcare**	**Buzzy® XL Healthcare**	**Buzzy® Mini Personal**	**Buzzy® XL Personal**	**Buzzy® Mini Healthcare**	**Buzzy® XL Healthcare**	**Buzzy® Mini Personal**	**Buzzy® XL Personal**	**Buzzy® Pro**
Indications for Use	Control pain associated with injections, venipuncture, IV starts, cosmetic injections and the temporary relief of minor injuries (muscle or tendon aches, splinters and bee stings). Also intended to treat myofascial pain caused by trigger points, restricted motion and muscle tension				To control pain associated with needle procedures (e.g., injections, vascular access, cannulation, lab draws, blood donation, dialysis, cosmetic and dental injections) and the temporary relief of minor injuries (muscle or tendon aches, splinters, and bee stings).				
Age(s)	Patients 4 years and older.				Patients 1 year and older when used with cold pack.				
Size (in)	2⅞" x 1⅞" x ⅞"	3¼" x 2⅛" x 1⅛"	2⅞" x 1⅞" x ⅞"	3¼" x 2⅛" x 1⅛"	2⅞" x 1⅞" x ⅞"	3¼" x 2⅛" x 1⅛"	2⅞" x 1⅞" x ⅞"	2⅞" x 1⅞" x ⅞"	3" x 2¼" x ¾"
Mechanism of Action	Mechanical vibration with cold therapy	Mechanical vibration with cold therapy	Mechanical vibration with cold therapy	Mechanical vibration with cold therapy	Mechanical vibration with cold therapy[1]	Mechanical vibration with cold therapy[1]	Mechanical vibration with cold therapy[1]	Mechanical vibration with cold therapy[1]	Mechanical vibration with cold therapy[1]
Vibration Settings	A: 0.1 m/s^2 F: 200±10 Hz	A: 0.1 m/s^2 F: 200±10 Hz	A: 0.1 m/s^2 F: 200±10 Hz	A: 0.1 m/s^2 F: 200±10 Hz	A: 0.1 m/s^2 F: 200±10 Hz[1]	A: 0.1 m/s^2 F: 200±10 Hz[1]	A: 0.1 m/s^2 F: 200±10 Hz[1]	A: 0.1 m/s^2 F: 200±10 Hz[1]	A: 0.1 m/s^2 F: 200±10 Hz[1]
Vibration Mode	Continuous or intermittent vibration	Continuous vibration	Continuous vibration	Continuous vibration	Continuous or intermittent vibration[1]	Continuous vibration[1]	Continuous vibration[1]	Continuous vibration[1]	Continuous vibration[1]
Power On/Off	Automatic shut-off after 3 min.	Manual power switch	Automatic shut-off after 3 min.	Manual power switch	Automatic shut-off after 3 min.[1]	Manual toggle power switch[1]	Automatic shut-off after 3 min.[1]	Manual toggle power switch[1]	Manual toggle power switch[1]
Patient Use	Multi-patient	Multi-patient	Single patient	Single patient	Multi-patient	Multi-patient	Single patient	Single patient	Multi-patient
Accessories Included	Ice packs Hands-free strap	Ice packs Hands-free strap	Ice packs	Ice packs Hands-free strap	ice packs Hands-free strap[2]	ice packs Hands-free strap[2]	Ice packs[1]	Ice packs Hands-free strap[1]	Ice packs Hands-free strap[2]
OTC / Rx	OTC	OTC	OTC	OTC	OTC[1]	OTC[1]	OTC[1]	OTC[1]	OTC[1]

[1] Identical to predicate device

[2] Similar to predicate device. No new questions of safety and effectiveness.

[3] Similar to predicate device. Non-clinical or clinical testing was submitted to support the change in technology.

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Table 2. Comparison of the subject (VibraCool) and predicate (Buzzy®) devices								
	Predicate Device (K130631)				Subject Device (K202993) - VibraCool			
Model names	**Buzzy® Mini Healthcare**	**Buzzy® XL Healthcare**	**Buzzy® Mini Personal**	**Buzzy® XL Personal**	**VibraCool Easy Fit**	**VibraCool Extended**	**VibraCool Plantar**	**VibraCool Flex**
Indications for Use	Control pain associated with injections, venipuncture, IV starts, cosmetic injections and the temporary relief of minor injuries (muscle or tendon aches, splinters and bee stings). Also intended to treat myofascial pain caused by trigger points, restricted motion and muscle tension				VibraCool is intended for the temporary relief of minor injuries (muscle or tendon aches) and the treatment of myofascial pain post-surgery. It is also indicated for use prior to or during physical therapy to treat myofascial pain caused by trigger points, restricted motion and muscle tension.			
Age(s)	Patients 4 years and older.				Patients 4 years and older when used with cold pack. Patients 12 and older with hot pack.			
Size (in)	2⅞" x 1⅞" x ⅞"	3¼" x 2⅛" x 1⅛"	2⅞" x 1⅞" x ⅞"	3¼" x 2⅛" x 1⅛"	2⅞" x 1⅞" x ⅞"	3¼" x 2⅛" x 1⅛"	3¼" x 2⅛" x 1⅛"	3¼" x 2⅛" x 1⅛"
Mechanism of Action	Mechanical vibration with cold therapy	Mechanical vibration with cold therapy	Mechanical vibration with cold therapy	Mechanical vibration with cold therapy	Mechanical vibration with cold therapy[3]	Mechanical vibration with cold therapy[3]	Mechanical vibration with cold therapy[3]	Mechanical vibration with heat or cold therapy[3]
Vibration Settings	A: 0.1 m/s^2 F: 200±10 Hz	A: 0.1 m/s^2 F: 200±10 Hz	A: 0.1 m/s^2 F: 200±10 Hz	A: 0.1 m/s^2 F: 200±10 Hz	A: 0.1 m/s^2 F: 200±10 Hz[1]	A: 0.1 m/s^2 F: 200±10 Hz[1]	A: 0.1 m/s^2 F: 200±10 Hz[1]	A: 0.1 m/s^2 F: 200±10 Hz[1]
Vibration Mode	Continuous or intermittent vibration	Continuous vibration	Continuous vibration	Continuous vibration	Continuous vibration[1]	Continuous vibration[1]	Continuous vibration[1]	Continuous vibration[1]
Power On/Off	Automatic shut-off after 3 min.	Manual power switch	Automatic shut-off after 3 min.	Manual power switch	Automatic shut-off after 10 min.[2]	Manual toggle power switch[1]	Manual toggle power switch[1]	Manual toggle power switch[1]
Patient Use	Multi-patient	Multi-patient	Single patient	Single patient	Single patient[1]	Single patient[1]	Single patient[1]	Single patient[1]
Accessories Included	Ice packs Hands-free strap	Ice packs Hands-free strap	Ice packs	Ice packs Hands-free strap	Two-chamber ice pack Compression strap[2]	Four-chamber ice pack Compression strap[2]	Single-chamber ice pack D-ring strap[2]	Two-chamber ice pack Heat pack Neoprene pocket[2]
OTC / Rx	OTC	OTC	OTC	OTC	OTC[1]	OTC[1]	OTC[1]	OTC[1]

[1] Identical to predicate device

[2] Similar to predicate device. No new questions of safety and effectiveness.

[3] Similar to predicate device. Non-clinical or clinical testing was submitted to support the change in technology.

Table 3. Comparison of the subject (VibraCool Pro) and predicate (Buzzy®) devices								
	Predicate Device (K130631)				**Subject Device (K202993) – VibraCool Pro**			
Model Names	**Buzzy® Mini Healthcare**	**Buzzy® XL Healthcare**	**Buzzy® Mini Personal**	**Buzzy® XL Personal**	**VibraCool Pro DME (Durable Medical Equipment)**	**VibraCool Pro UE (Upper Extremity)**	**VibraCool Pro LE (Lower Extremity)**	**VibraCool Pro Healthcare VibraCool Pro Healthcare**
Indications for Use	Control pain associated with injections, venipuncture, IV starts, cosmetic injections and the temporary relief of minor injuries (muscle or tendon aches, splinters and bee stings). Also intended to treat myofascial pain caused by trigger points, restricted motion and muscle tension				VibraCool is intended for the temporary relief of minor injuries (muscle or tendon aches) and the treatment of myofascial pain post-surgery. It is also indicated for use prior to or during physical therapy to treat myofascial pain caused by trigger points, restricted motion and muscle tension.			
Age(s)	Patients 4 years and older.				Patients 4 years and older when used with cold pack. Patients 12 and older with hot pack.			
Size (in)	2⅞" x 1⅞" x ⅞"	3¼" x 2⅛" x 1⅛"	2⅞" x 1⅞" x ⅞"	3¼" x 2⅛" x 1⅛"	3" x 2¼" x 3/4"	3" x 2¼" x 3/4"	3" x 2¼" x 3/4"	3" x 2¼" x 3/4"
Mechanism of Action	Mechanical vibration with cold therapy	Mechanical vibration with cold therapy	Mechanical vibration with cold therapy	Mechanical vibration with cold therapy	Mechanical vibration with cold therapy[3]	Mechanical vibration with heat and cold therapy[3]	Mechanical vibration with heat and cold therapy[3]	Mechanical vibration with cold therapy[3]
Vibration Settings	A: 0.1 m/s^2 F: 200±10 Hz	A: 0.1 m/s^2 F: 200±10 Hz	A: 0.1 m/s^2 F: 200±10 Hz	A: 0.1 m/s^2 F: 200±10 Hz	A: 0.1 m/s^2 F: 200±10 Hz[1]	A: 0.1 m/s^2 F: 200±10 Hz[1]	A: 0.1 m/s^2 F: 200±10 Hz[1]	A: 0.1 m/s^2 F: 200±10 Hz or 100±10 Hz[1, 2]
Vibration Mode	Continuous or intermittent vibration	Continuous vibration	Continuous vibration	Continuous vibration	Continuous vibration[1]	Continuous vibration[1]	Continuous vibration[1]	Continuous vibration[1]
Power On/Off	Automatic shut-off after 3 min.	Manual power switch	Automatic shut-off after 3 min.	Manual power switch	Manual toggle power switch[1]	Manual toggle power switch[1]	Manual toggle power switch[1]	Manual toggle power switch[1]
Patient Use	Multi-patient	Multi-patient	Single patient	Single patient	Multi-patient[1]	Single patient[1]	Single patient[1]	Multi-patient[1]
Accessories Included	Ice packs Hands-free® strap	Ice packs Hands-free® strap	Ice packs	Ice packs Hands-free strap	Ice pack[2]	Ice pack Heat pack D-ring strap[2]	Ice pack Heat pack Compression strap[2]	Ice packs Straps[2]
OTC / Rx	OTC	OTC	OTC	OTC	OTC / Rx[2]	OTC / Rx[2]	OTC / Rx[2]	OTC / Rx[2]

[1] Identical to predicate device

[2] Similar to predicate device. No new questions of safety and effectiveness.

[3] Similar to predicate device. Non-clinical or clinical testing was submitted to support the change in technology.

SUBSTANTIAL EQUIVALENCE DISCUSSION

- Addition of VibraCool

The addition of VibraCool does not raise new or different questions of safety and effectiveness. Like the devices cleared in K130631, VibraCool uses the same vibration device and is intended for external use utilizing vibration and heat or cold therapy to relieve pain. VibraCool is to be used on a wider range of locations on the body (e.g., knees, ankles, and feet). However, it is still the same external, intact skin- contacting device. Additionally, questions regarding the efficacy of VibraCool are addressed by clinical data from several published clinical studies. These data support the efficacy of the combination of vibration and heat or cold therapy for physical therapy. Labeling will include a limit of 4 years and older patients when using cold.

The addition of a commercially available hot pack as a heat therapy mode with VibraCool Flex and VibraCool Pro Upper/Lower Extremity when used for the temporary relief of minor injuries (muscle or tendon aches) and the treatment of myofascial pain post-surgery and during physical therapy does not raise new or different questions of safety or effectiveness. The safety and effectiveness of VibraCool used with heat therapy are addressed by clinical data from several published clinical studies. Labeling will include a limit of 12 and older patients when using heat, and a shelf life of 3 years.

- Addition of "Pro" Lines of Buzzy and VibraCool

The Buzzy Pro and VibraCool Pro are identical to the predicate device in terms of materials, vibration motor, circuitry, functionality, and intended use. They differ only in shape but are comparable in size to the predicate devices. Specifically, the Pro devices are distinguished by their rectangular shape to offer users a more professional looking alternative to the bee-shape of the other devices. It may be used with the same accessories as the other VibraCool devices. There are no new questions regarding safety and effectiveness.

- Updated Indications for Use Statements
  - Buzzy:

    The updated statement uses "needle procedures" to capture the range of scenarios in which Buzzy would be used and then provides examples of these types of procedures. Vascular access, cannulation, and dialysis are equivalent to IV starts and lab draws and blood donation is equivalent to venipuncture. Dental injections are another type of needle procedure which has been clinically investigated for this use. The data support this indication as subjects reported a meaningful reduction in pain when using Buzzy compared to no intervention at all.

  - VibraCool:

    The indication for use statement associated with the predicate device (K130631) refers to temporary relief of minor injuries such as muscle or tendon aches. K130631's IFU also includes treating myofascial pain caused by trigger points, muscle tension and restricted motion. The updated VibraCool's IFU (K202993) includes treatment of myofascial pain post-surgery and treatment of myofascial pain caused by trigger points, restricted motion, and muscle tension prior to or during physical therapy. This change does not result in new intended use, as the subject VibraCool devices are, as the predicate devices, intended to provide temporary relief of minor overuse injuries and tendinitis. Rather, the new indications for use provide clarification on the context of use of the VibraCool devices. This change is therefore not expected to affect the safety and effectiveness of the subject device.

  - Patient population:

    When used with the cold pack, the Buzzy subject devices are indicated for use on patients of

ages 1 and older, while the predicate device is indicated for patients of ages 4 and older. The use of a hot pack with the VibraCool or VibraCool Pro subject devices are indicated for use on patients 12 and up. This change in intended population does not raise new questions of safety and effectiveness. The labeling for heat packs will be for age 12 and up.

SUMMARY OF NON-CLINICAL TESTING

The following tests were performed to demonstrate safety based on current industry standards:

- Temperature testing (device surface and skin surface) over the entire treatment period, after the initial activation and after the maximum number (5) of boil-cool reuse cycles.
- Seal integrity/strength testing of hot packs
- Shelf stability tests of hot packs
- Electrical safety and electromagnetic compatibility:
    - IEC 60601-1 and AAMI/IEC 60601-1:2005 + AMD 1:2012 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
    - IEC 60601-1-11:2015 Medical Electrical Equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
    - CFR 47, FCC Part 15 Radio Frequency Devices, Subpart B:2017 Unintentional Radiators

SUMMARY OF CLINICAL TESTING

The performance of the Buzzy devices on pediatric populations above the age of 1 year old was evaluated in various clinical settings for pain relief during vascular access and needle-related procedures. A study in infants published in a peer-reviewed scientific publication is summarized in Table 4 below.

Table 4. Clinical Studies – Pain Indication

Study Objective	Results	Reference
Prospective, randomized study evaluating the effect of Buzzy on the pain of infants receiving MMR vaccine using the total "facial expression, leg movements, activity, cry, and consolability" (FLACC) scale rated by nurses and parents. Study Subjects: 12-month olds N = 60	The pulse was lower after injection for Buzzy (p=.037). Average pain rated with FLACC (Faces, Legs, Arms, Cry, Console) was lower during (6.07 (SD = 2.34)) and after vaccination (1.13 (SD = 1.53)) in the Buzzy group than control (9.07 (SD = 1.2)), (4.2 (SD = 1.24)), respectively (p=.001)	Siktas, O. Uysal, G. "The Effect of Buzzy Application on Pain Level During Vaccine Injection in Infants. J Nurs Care Qual (2023) 38(1):E9-E15 *DOI: 10.1097/NCQ.0000000000000656*

CONCLUSION

Based on the testing performed to confirm electromagnetic compatibility and electrical safety, and the clinical evidence described in published clinical studies, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate devices. The similar indications for use, technological characteristics, and performance characteristics for the proposed Buzzy, Buzzy Pro, VibraCool, and VibraCool Pro devices are assessed to be substantially equivalent to the predicate devices.