August 1, 2025

Dentalhitec
℅ Adrienne Von Foller
Consultant
QRS Solutions LLC
966 E. 2050 N
Ogden, Utah 84414

Re: K243427
Trade/Device Name: QuickSleeper 5
Regulation Number: 21 CFR 872.4475
Regulation Name: Spring-Powered Jet Injector
Regulatory Class: Class II
Product Code: EGM, EJI
Dated: October 7, 2024
Received: November 5, 2024

Dear Adrienne Von Foller:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K243427

Device Name

QuickSleeper 5

Indications for Use *(Describe)*

Administration of local anesthesia for dental procedures.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# K243427 - 510(k) Summary

| | |
|---|---|
| **Name of 510(k) Owner:** | Dentalhitec |
| **Address of Submitter:** | Rue De Champs Blanc<br>Mazieres En Mauges<br>Maine-Et-Loire, France 49280 |
| **Submitter Contact:** | Olivier Villette,<br>General Manager / CEO |
| **Prepared by (for contact):** | Adrienne von Foller<br>Regulatory Affairs Consultant<br>QRS Solutions, LLC<br>Telephone: (801) 916-8188<br>Email: AVonFoller@qrssolutionsllc.com |
| **Date Prepared:** | July 29, 2025 |
| **Submission Type:** | Traditional 510(k) |
| **Proprietary Name:** | QuickSleeper 5 |
| **Common Name(s):** | Injector, Jet, Mechanical-Powered |
| **Classification:** | 21 CFR 872.4475, Spring-powered jet injector |
| **Device Class:** | Class II |
| **Device Product Code:** | EGM, EJI |
| **Predicate Device:** | K083811 – RA-5 ANESTO Handpiece |
| **Reference Device:** | K061904 – The WAND STA System |

## Device Description

The Dentalhitec QuickSleeper 5 (QS5) is indicated for the administration of local anesthesia for dental procedures using computer-controlled handpiece and wireless foot pedal. The QuickSleeper5 is a reusable injection device, allowing intraosseous and mucosal injection of anesthetic within the oral cavity. The QS5 functionality includes injection, aspiration, and rotation. The handheld syringe device's electronic interface provides the user with information on selected injection speed and injection site resistance. The rotational movement allows the needle to pass through dense tissue.

## Indications for Use

Administration of local anesthesia for dental procedures.

### Technological Characteristics

The electronic motor of the QuickSleeper 5 system provides control over the delivery of anesthetic, with adjustable speed and pressure settings that allow the practitioner to optimize the injection process based on the specific needs of the procedure. It also includes an intraosseous setting, which enables rotational movement of the needle for bone penetration.

The ergonomic handpiece is designed with a "pen-like" grip. The system features both audible and visual indicators to provide real-time feedback to the practitioner. It is compatible with the manufacturer's needles and accommodates standard anesthetic cartridges of 1.7 mL and 1.8 mL sizes compatible with ISO 11499.

The system is equipped with a wireless foot pedal, handpiece mount, and handpiece stand. The control box includes firmware which includes programmable settings as well as basic presets that allow for varying injection techniques based on the specific needs of the procedure.

### Substantial Equivalence

This candidate device, QuickSleeper 5, and predicate device are substantially equivalent and have the same intended use. Technological and performance differences do not raise any new questions of safety or effectiveness. Differences in technological characteristics between the QuickSleeper 5 and the predicate device do not affect substantial equivalence, including computer-controlled delivery of anesthesia, wireless foot pedal, and user interface elements. Additionally, a reference device has been included to provide a comparison of the similarities in technological characteristics to a legally marketed computer-controlled device. Comparison analysis of these devices are presented in the table below.

| | **Candidate Device** | **Predicate Device** | **Reference Device** |
|---|---|---|---|
| **Trade Name** | QuickSleeper 5 | RA-5 ANESTO Handpiece | The WAND STA System |
| **Manufacturer** | Dentalhitec | W&H Dentalwerk | Milestone Scientific, Spintech LLC |
| **510(k) Number** | K243427 | K083811 | K061904 |
| **Regulation** | 21 CFR 872.4475<br>Spring-powdered jet injector | 21 CFR 872.4475<br>Spring-powdered jet injector | 21 CFR 872.6770<br>Cartridge, Syringe |
| **FDA Product Code** | EGM, EJI | EGM | EJI |
| **Classification** | Class II | Class II | Class II – 510(k) Exempt |
| **Intended Use** | Local anesthesia injection in dentistry | Local anesthesia injection in dentistry | Local anesthesia injection in dentistry |

# K243427 - 510(k) Summary

| | | | |
|---|---|---|---|
| **Indications for Use** | Administration of local anesthesia for dental procedures | Drilling system to perforate cortical bone in order to administer local anesthesia in spongiosa. Application in dentistry. | To inject local anesthetic agents subcutaneously or intramuscularly for dental applications |
| **Prescription Use?** | Rx Only | Rx Only | Rx Only |
| **Target Patient Population** | Adult and pediatric (4 years old and older) | Adult and pediatric | Adult and pediatric |
| **Use Environment** | Professional healthcare facility | Professional healthcare facility | Professional healthcare facility |
| **Mode of Action** | **Needle Placement**<br>• Needle rotation is used for intraosseous access.<br>• Needle is placed through mucosa next to bone.<br>**Needle Rotation**<br>• Foot-controlled needle operation (motorized in handpiece)<br>**Injection**<br>• Drive Screw creates forward translation of plunger which transmits movement into the anesthetic cartridge.<br>• Injection Modes: The anesthetic within the cartridge is ejected through the needle at the end of the container through one of three injection modes: Hi, IO or Lo.<br>**Aspiration**<br>• Computer controls allow for regulation of aspiration via foot pedal | **Needle Placement**<br>• Needle rotation is used for intraosseous access.<br>• Needle is placed through mucosa next to bone<br>**Needle Rotation**<br>• Separate air driven and electrical dental motors with maximum speed 2Ncm of torque rotates and drills through bone.<br>**Injection**<br>• Anesthetic is manually injected by repeatedly pressing the dosage lever. | **Needle Placement**<br>• Needle is placed based on procedure being performed.<br>**Injection**<br>• Foot pedal controls injection flow rate (slight vs. modest pressure)<br>• Computer controls allow for regulation of flow rates and pressure during injection<br>**Aspiration**<br>• Computer controls allow for regulation of aspiration via foot pedal |
| **Power Source** | Alternating power source providing 100-240 V | Powered by separate dental motor | Alternating power source providing 100-240 V |
| **Compatible Accessories** | - Effitec single-use needles (30G 9mm, 30G 16mm, 27G 35mm) only<br>- Dental anesthetic cartridge (ISO 11499 compatible) | - W&H applicable, single-use injection needles<br>- Dental anesthetic cartridge (ISO 11499 compatible) | Anesthetic capsules |

**Discussion of Non-Clinical Tests Performed**

To demonstrate substantial equivalence, the subject device met the acceptance criteria for the following non-clinical testing.

Software Verification testing including:

- Injection testing
- Audio indicators
- Option selection
- Standby function
- Conformance to IEC 62304

Device safety and performance testing including:

- Handpiece dimensions
- Injection and perforation performance
- Assembly (component connections)
- Cleaning, disinfection, and sterilization validations
- Biocompatibility

The electrical safety and effectiveness of the QuickSleeper 5 have been demonstrated through testing conducted in accordance with the following standards:

- IEC 60601-1
- IEC 60601-1-2
- IEC 60601-4-2
- IEC 60601-1-6

**Discussion of Usability Testing**

To evaluate the usability of the QuickSleeper 5 system, a comprehensive simulated use approach was taken which involved analyzing various aspects of user interaction. This included a detailed examination of user tasks and goals and collecting user feedback through direct input and observations.

**Conclusion**

Based on the comprehensive information and data provided in this submission, we conclude that the QuickSleeper 5 is substantially equivalent to the predicate device. Based on similar indications for use, technological characteristics, and non-clinical performance testing, the QuickSleeper 5 demonstrates substantial equivalence to the predicate device.