February 22, 2023

Saeshin Precision Co., Ltd.
℅ Sanghwa Myung
Regulatory Affair Consultant
E&M
D-1474, 230, Simin-daero, Dongan-gu
Anyang, Gyeonggi-do 14067
South Korea

Re: K221741
Trade/Device Name: TRAUS Air Dental Handpiece
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EFB
Dated: November 18, 2022
Received: November 25, 2022

Dear Sanghwa Myung:

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,

Michael E. Adjodha -S

Michael E. Adjodha, M.ChE.
Assistant Director
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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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K221741

Device Name
TRAUS Air Dental Handpiece

Indications for Use *(Describe)*
This air-powered dental handpiece is intended for removal of carious material, cavities and crown preparations, removal of filings, processing of tooth, restoration of surfaces and as a surgical tool for third molar removal procedures.
It is designed for use by a trained professional in the field of general dentistry.

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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# 510(k) Summary

# K221741

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Primary Contact: Sanghwa Myung

**Date 510(k) summary prepared: February 21, 2023**

Common Name: Handpiece, Air-Powered, Dental
Trade Name: TRAUS Air Dental Handpiece
Classification: I
Product Code: EFB
Classification Panel: Dental
Regulation Numbers: 21 CFR 872.4200
Regulation Name: Dental handpiece and accessories

**Description of Device:**

The TRAUS Air Dental handpieces are air driven dental handpieces for the use by a trained dental professional. The devices are air-powered handpieces that are reusable and designed accordance with international standard. The devices can be sterilized by the pre-vacuum steam autoclave methods that have been validated. Through the coupling connected to a dental unit, the proposed dental handpiece receive air for functionality of the high-speed turbine. They also receive cooling water for cutting through one port and light for illumination through another port.
Using in combination with dental unit chair, it is possible to use by installing the instrument at air handpiece according to purpose. It is possible to change the rotation speed by adjusting the flowing air.

**Indication for use:**

This air-powered dental handpiece is intended for removal of carious material, cavities and crown preparations, removal of filings, processing of tooth, restoration of surfaces and as a surgical tool for third molar removal procedures.
It is designed for use by a trained professional in the field of general dentistry.

**Predicate Device:**

Manufacturer: KaVo do Brasil Industria e Comercio Ltda

510(k) Number: K141576
Trade Name: Maxima PRO 45L
Common Name: Handpiece, Air-Powered, Dental
Regulation Name: Dental handpiece and accessories
Regulation Numbers: 21 CFR 872.4200
Product Code: EFB
Classification: Class I

**Substantial Equivalence:**
Comparison table is as follows.

**Table 1: Substantial equivalence comparison**
**1) Predicate Device**

| Contents | Subject Device | Predicate Device |
|---|---|---|
| 510(k)Number | Not available | K141576 |
| Trade Name | TRAUS Air Dental Handpiece | Maxima PRO 45L |
| Indication for Use | This air-powered dental handpiece is intended for removal of carious material, cavities and crown preparations, removal of filings, processing of tooth, restoration of surfaces and as a surgical tool for third molar removal procedures.<br>It is designed for use by a trained professional in the field of general dentistry. | This air-powered dental handpiece is intended for removal of carious material, cavities and crow preparations, removal of filings, processing of tooth, restoration of surfaces and as a surgical tool for third molar removal procedures.<br>It is designed for use by a trained professional in the field of general dentistry. |
| Operation principal | Through the tube and the coupling connected to a dental unit, the airpowered handpiece<br>receives the air for operating the high speed turbine, the cooling water for cutting treatment<br>through one port and light for illumination the operation area. | Through the tube and the coupling connected to a dental unit, the airpowered handpiece<br>receives the air for operating the high speed turbine, the cooling water for cutting treatment<br>through one port and light for illumination the operation area. |
| Head Size | ATN400: Ø11.2 x13.55mm<br>CAB10LK: Ø11.2 x13.7m<br>CAB10LN: Ø11.2 x14.2m<br>CAB20ND M4: Ø11.2 x13.55m<br>CAB20ND B2: Ø11.2 x13.55m | Head size-Height: 14,6 mm<br>Head size-Diameter: 12,5 mm |
| Type of chuck | ISO1797-2017<br>4.Classification<br>-Type 3: FG(Friction Grip) | Push Button |
| Water ports | CAB10LN/CAB10LK/CAN10NN /CAB20ND M4 : 4hole<br>CAB20ND B2: 1hole | 1 hole |
| Coupling Dimensions | Length with coupling: | Length with coupling: |

| | | |
|---|---|---|
| | TRAUS CAN10NN + TRAUS CP10NQ<br>Approx. 129.59 mm<br>TRAUS CAB10LN + TRAUS CP10LN<br>Approx. 143.53 mm<br>TRAUS CAB10LK + TRAUS CP10LK<br>Approx. 138.97 mm | Approx. 121 mm |
| Chemical composition of the patient- contacting portions of the device | 303F | 303F |
| Light Intensity | Approximately 7,000 LUX | Approximately 25,000 LUX |
| Bur retention force | up to 24 Ncm | up to 24 Ncm |
| Operating Pressure | 43.5 psi (0.3Mpa) recommended | 40 ± 1.45 psi recommended |
| Idling Speed | 360,000 - 440,000 rpm | 380,000 - 420,000 rpm |
| Head angle | 90-degree | 45-degree |
| Compliance to Standards | Complies with ISO 14457 and ISO 9168 | Complies with ISO 14457 and ISO 9168 |
| Lubricant | Pana Plus Spray | KaVo Spray<br>Henry Schein Spray & Clean |

**Biocompatibility:** Materials tested in accordance with 10993-1 are used and materials that have been confirmed to be biologically safe are used.

Patient contact parts of the TRAUS Air Dental Handpiece are as follows.

| **Parts** | **Raw Material** | **Surface Treatment** | **Patient contact** | **Duration of contact by ISO 10993-1** |
|---|---|---|---|---|
| Head | SUS303F | Hard Chrome coated | Yes | Limited<br>(<24 hours) |

1) ISO 10993-1: 2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
2) ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
3) ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
4) ISO 10993-12:2012 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials

**Non-clinical Performance Data**:

- The bench tests were performed in order to ensure the performance of the TRAUS Dental Air Handpieces (ATN400,CAB10LK,CAB10LN,CAB20ND M4,CAB20ND B2) verify conformity to ISO 14457 and demonstrate substantial equivalence to the predicates. ATN400,CAB10LK,CAB10LN,CAB20ND M4,CAB20ND B2 samples were compliant with ISO 14457: 2017 Dentistry - Handpieces and Motors and demonstrated substantial equivalence to the predicates.
- Sterilization has been validated in conformance to the FDA recognized consensus standard ISO 17665-1:2006 Sterilization of health care products – moist heat – Part 1: requirements for the development, validation and routine control of a sterilization process for medical devices. Cleaning validation testing is performed in accordance with recommended evaluations as listed in AAMI TIR30, AAMI TIR12, and Guidance for Industry and FDA Staff - Processing/Reprocessing Medical Devices in Health Care Settings.
- ISO 9168:2009 Dentistry — Hose connectors for air driven dental handpieces, device's hose connection has been verified by standard of ISO 9168.

**Clinical Data:** No clinical performance testing was performed.

**Conclusion**

The performance of TRAUS Air Dental Handpiece meets the requirements of the non-clinical bench testing conducted to support substantial equivalence. Based on the available information, the subject device and the predicates are similar indication for use, operational principal, performance data.
In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification that we conclude that substantially equivalent with predicate device.