January 9, 2025

Changzhou Finno Medical Technology Co., Ltd.
℅ Jie Zhu
RA Manager
First Floor East and Third Floor, Building 5
No. 28 Yandanghe Road, Xinbei District
Changzhou, Jiangsu 213000
CHINA

Re: K242805
Trade/Device Name: Dental Cone-beam Computed Tomography (model: FinScan F350)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: OAS
Dated: September 13, 2024
Received: December 11, 2024

Dear Jie Zhu:

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnsotic X-ray Systems Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
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: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K242805

Device Name
Dental Cone-beam Computed Tomography (model: FinScan F350)

Indications for Use *(Describe)*
FinScan F350 is CBCT, panoramic and cephalometric x-ray imaging system. The device is intended to radiographic examination of the dento-maxillofacial and TMJ structure for diagnostic support for adult and pediatric patients. Cephalometric image also includes wrist to obtain carpus images for growth and maturity assessment for orthodontic treatment.
The device is to be operated and used by dentists or other legally qualified health care professionals.

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.

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# 510(k) Summary

## 1. Submitter


| | |
|---|---|
| Manufacturer: | Changzhou Finno Medical Technology Co., Ltd.<br>First Floor East and Third Floor, Building 5, No. 28 Yandanghe Road,<br>Xinbei District, 213000 Changzhou, Jiangsu, China |
| Phone: | +86 400-677-9698 |
| Contact Person: | Jie Zhu |
| E-mail: | amanda@sifary.com |


| | |
|---|---|
| Date Prepared: | September 13, 2024 |

## 2. Device

| | |
|---|---|
| Name of Device: | Dental Cone-beam Computed Tomography (model: FinScan F350) |
| Common Name: | Dental Cone-beam Computed Tomography |
| Classification Name: | Computed tomography x-ray system |
| Regulation Number: | 21 CFR Part 892.1750 |
| Regulatory Class: | Class II |
| Product Code: | OAS |
| Review Panel: | Radiology |

## 3. Predicate Device

| | |
|---|---|
| Trade/Device Name: | RCT700 |
| Classification Name: | Computed tomography x-ray system |
| Regulation Number: | 21 CFR Part 892.1750 |
| Regulatory Class: | Class II |
| Product Code: | OAS |
| Review Panel: | Radiology |
| Manufacturer: | RAY Co., Ltd |
| 510 (k) Number: | K213226 |

No reference devices were used in this submission.

## 4. Device Description

Dental Cone-beam Computed Tomography (model: FinScan F350) uses cone-beam computed tomography (CBCT) technology through X-ray cone-beam, panoramic radiography, cephalometric radiography to produce images of the dento-maxillofacial and TMJ structure to provides diagnostic details for dental clinics and dental hospitals.

This product mainly consists of column, rotating unit, tube head assembly, CBCT/panoramic detector,

cephalometric detector, the workstation and image processing software.

## 5. Indications for Use

FinScan F350 is CBCT, panoramic and cephalometric x-ray imaging system. The device is intended to radiographic examination of the dento-maxillofacial and TMJ structure for diagnostic support for adult and pediatric patients. Cephalometric image also includes wrist to obtain carpus images for growth and maturity assessment for orthodontic treatment.

The device is to be operated and used by dentists or other legally qualified health care professionals.

## 6. Intended patient population

The patient population can be the possible person who can be taken X-ray diagnostic radiation exposure.

There is no restriction for ethnic group, Gender, weight, health, or condition.

We recommend patients for X-ray diagnostic radiation exposure to be over 5 years old.

Radiation exposure is a concern in both adults and children. However, children are more sensitive to radiation than adults and have a longer life expectancy.

Radiation risk is higher in young patients, as they have more rapidly dividing cells than adults.

The younger the patient, the more sensitive they are. Using the same exposure parameters on a child as used on an adult may result in larger doses to the child. There is no need for these larger doses to children, and X-ray settings can be adjusted to reduce dose significantly while maintaining diagnostic image quality.

Please refer the web pages regarding additional pediatric information.

FDA's Pediatric X-ray Imaging webpage:

http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures

## 7. Comparison of Technological Characteristics with the Predicate Device

The comparison between the overall specifications of predicate device (RCT700) and the new device (FinScan F350) is shown in the following table.

| Parameter | Subject Device | Predicate Device |
|---|---|---|
| Manufacturer | Changzhou Finno Medical Technology Co., Ltd. | RAY Co., Ltd. |
| Device name | FinScan F350 | RCT700 |
| 510(K) Number | / | K213226 |
| Indications for Use | FinScan F350 is CBCT, panoramic and cephalometric x-ray imaging system. The device is intended to radiographic examination of the dento-maxillofacial and TMJ structure for diagnostic | RCT700 is CBCT and panoramic x-ray imaging system with cephalometric. Which is intended to radiographic examination of the dento-maxillofacial, sinus, TMJ, Airway and ENT |

| | | | |
|---|---|---|---|
| | | support for adult and pediatric patients. Cephalometric image also includes wrist to obtain carpus images for growth and maturity assessment for orthodontic treatment.<br>The device is to be operated and used by dentists or other legally qualified health care professionals. | structure for diagnostic support for adult and pediatric patients. And a model scan is included as an option. Cephalometric image is also includes wrist to obtain carpus images for growth and maturity assessment for orthodontic treatment.<br>The device is to be operated and used by dentists or other legally qualified heath care professionals. |
| Mode of Operation | | Continuous operation/intermittent loading | Continuous operation with intermittent, stated permissible loading |
| 3D Technology | | CBCT Cone beam Computed Tomography | CBCT Cone beam Computed Tomography |
| Performance Specification | | 1) CBCT Computed tomography<br>2) Panoramic<br>3) Cephalometric (scan type) | 1) CBCT Computed tomography<br>- Patient<br>2) Panoramic<br>3) Cephalometric (optional)<br>- One shot type<br>- Scan type |
| Detector Type | CT | TFT | TFT |
| | Panoramic | TFT | TFT |
| | Cephalometric | CMOS (Scan type) | CMOS (Scan type)<br>TFT (One shot type) |
| Main Components | | - Column<br>- Handle<br>- Touchpad<br>- Chin rest and bite fork, Chin rest (TMJ), Chin rest (Toothless)<br>- Temple support<br>- CBCT/ Panoramic detector<br>- Laser light area<br>- X-ray exposure light<br>- Rotating unit<br>- Tube head assembly<br>- Nasal rod<br>- Ear rod<br>- Cephalometric detector | - Ceph Apparatus<br>- Vertical Carriage<br>- Rotator<br>- X-RAY Generator<br>- X-ray tube<br>- High Frequency Generator<br>- Column<br>- Touch monitor (panel)<br>- Detector<br>- Chinrest<br>- Head rest<br>- Automatic Collimator<br>- Exposure switch<br>- Emergency stop switch<br>- Console PC set |

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|---|---|---|---|
| | | - Emergency stop switch<br>- On/off switch<br>- Workstation | |
| Display Type | | No display | TFT LCD type(Normally black)<br>*1280x800 pixel |
| Class | | Class I with type B applied parts according to IEC 60601-1 | Class I with type B applied parts according to IEC 60601-1 |
| Focal size | | 0.5 | 0.5 |
| Field of View(CT) | | Max.160x100 mm | Max.160x100 mm |
| X-ray Tube Voltage | | 60~100kVp | 60~100kVp |
| X-ray Tube Current | | 6mA~10mA | 1~17mA |
| Total Filtration | | Min. 2.8 mm Al equivalent | Min. 2.8 mm Al equivalent |
| Detector Pixel Size | CT | 100μm | FXDD-0606CA: 119μm<br>Jupi0606X: 100μm |
| | Panoramic | 100μm | FXDD-0606CA: 119μm<br>Jupi0606X: 100μm |
| | Cephalometric | 100μm | Ceph (Scan)<br>XID-C24DC: 100μm<br><br>Ceph(One shot)<br>FXDD-1012CA: 124μm<br>FXRD-1717VA: 140μm |
| Scan Time | CT | General:18s<br>Fast: 9s | below 14sec |
| | Panoramic | Arch:14s<br>TMJ: 6s | below 14sec |
| | Cephalometric | Lateral, Frontal:8s<br>Carpus: 6s | Ceph[Scan type] : below 20sec<br>Ceph[One shot type]: below 2sec |
| Format Compatible | | DICOM 3.0 Format compatible | DICOM 3.0 Format compatible |
| Image Viewing Software | | FinScan (2D and 3D image processing software installed on the workstation);<br>FinScanFW (embedded software in the single chip of the host) | RayScan<br>(Cleared under K182614) |
| Image Acquisition | | Giga-Ethernet Network | Giga-Ethernet Network |
| Total Height | | Max 2,281mm | Max 2,296mm |
| Weight | | 220kg (485lb)±10% | Max 212.5kg (468.5lb) ± 10% |
| Applicable Standards | | IEC 60601-1<br>IEC 60601-1-3<br>IEC 60601-2-63 | IEC 60601-1<br>IEC 60601-1-3<br>IEC 60601-2-63 |

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| | IEC 60601-1-2 | IEC 60601-1-2 |

The above comparison table show that the subject and predicate devices have substantially similar technology characteristics. Differences show up in the display type, detector pixel size, scan time, and image viewing software. All of the parameters of the subject device comply with 21 CFR 1020.30, 1020.31, 1020.33 and related IEC standards. The differences of the device do not raise new issues of safety and effectiveness.

## 8. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

### Biocompatibility

For the biocompatibility of the parts that can come into contact with the patient, ISO 10993-1:2018 "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" has been considered. In clinical use, a disposable plastic firm is required to cover the Bite fork. The Bite fork is does not come in direct contact with the patient's oral tissue and teeth normally on the chance that contact does occur if the disposable cover is broken. The Chin rest, Chin rest (TMJ), Chin rest (Toothless), Temple support, Ear rod, Nasal rod come in direct contact with patient's intact skin surfaces. These parts are made of Polycarbonate (PC). The battery of testing included the following tests:

- Cytotoxicity
- Irritation
- Sensitization

According to the test results, no biocompatibility problem has been observed.

### Electrical Safety and Electromagnetic Compatibility (EMC)

The electrical safety and EMC data included in the submission is in compliance with the following FDA recognized standards:

- IEC 60601-1 Edition 3.2 2020-08
- ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 [Incl. AMD2:2021]
- IEC 60601-1-2 Edition 4.1 2020-09
- IEC/TR 60601-4-2 Edition 1.0 2016-05
- IEC 60601-1-3 Edition 2.2 2021-01
- IEC 60601-2-63 Edition 1.2 2021-05
- IEC 60601-1-6 Edition 3.2 2020-07

The laser light was tested to be conformed to IEC 60825-1:2014.

**Software Verification and Validation Testing**

Software architecture of FinScan F350 can be divided into two groups:

- Software installed on the workstation, which is used to control the imaging system to complete the case management and patient image acquisition, reconstruction, storage, browsing, processing and three-dimensional image reconstruction and processing process.
- Software embedded in the single chip of the host, which is used to control the motion of the device and the acquisition of image data.

Software verification and validation testing has been conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions", and "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions". The software documentation level for this device was considered as Basic Documentation Level, since a failure or flaw of software function could not present a hazardous situation with a probable risk of death or serious injury, either to a patient, user of the device, or others in the environment of use.

**Bench Testing**

Performance bench testing was conducted as part of design control to ensure the substantial equivalence of FinScan F350 to the predicate device. The testing was performed according to the requirements of 21 CFR Part 1020.30, 1020.31, 1020.33, IEC 61223-3-4 and IEC 61223-3-7, and FDA Guidance "Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices". The representative indicators for CT image quality, such as spatial resolution, CNR, and homogeneity were measured. The results demonstrate that the subject device is as safe, as effective, and perform as well as the predicate device.

**Clinical Considerations**

Clinical images acquired using FinScan F350 were evaluated by two US board certified experienced dentists to be of acceptable clinical effectiveness for the proposed indications for use. The results have been summarized in the clinical images evaluation report. The overall image quality was acceptable for all cases and image types in various imaging mode.

## 9. Conclusions

In reference to the comparison information provided in the substantial equivalence table, most of the technological characteristics of the subject device are similar with the predicate device. The differences have been addressed and analyzed with no new issues of safety and effectiveness raised. We believe that Dental Cone-beam Computed Tomography (model: FinScan F350) is safe and effective, and has no new indication for use. FinScan F350 is substantially equivalent to the predicate device.