Midmark Corporation
℅ Mr. Mark Kenar
Quality & Regulatory Affairs Manager
1001 Asbury Drive
BUFFALO GROVE IL 60089

August 6, 2020

Re: K201667
Trade/Device Name: Midmark Extraoral Imaging System (EOIS)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS, MUH
Dated: June 18, 2020
Received: June 19, 2020

Dear Mr. Kenar:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201667

Device Name
Midmark Extraoral Imaging System (EOIS)

Indications for Use *(Describe)*
The intended use of the Midmark EOIS is to provide dental radiographic examination to aid in the diagnosis of diseases of the teeth, jaw and oral structures. When the system is equipped with the cephalometric option, the system will provide cephalometric radiographic examinations for use in orthodontic treatment planning and evaluation. When the system is equipped with the CBCT option, the system will also provide volumetric and tomographic images of the oral and maxillofacial region, for diagnostic examination of teeth, jaws, oral structures, and some cranial bones.

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 – K201667

As required by the Safe Medical Devices Act (SMDA) of 1990 and in accordance with 21 CFR §807.92, a 510(k) summary is provided below with the required information.

5.1 Administrative Information

Device Name	Midmark Extraoral Imaging System (EOIS)
Date Summary Prepared	June 18, 2020
510(k) Sponsor Address	1001 Asbury Drive Buffalo Grove, IL 60089, USA
Contact Person	Mark Kenar
Trade Name	Extraoral Imaging System (EOIS)
Common Name	Extraoral X-ray System
Classification Name	21 CFR §892.1750 Computed tomography X-ray system (Product Code OAS) 21 CFR §872.1800 Extraoral source X-ray system (Product Code MUH)
Device Class	2
Review Panel	Radiology

5.2 Equivalent Predicate Comparators

Manufacturer Name	Trade Name	Regulation Name and Number	Device Class	Product Code	510(k) No.	Decision Date
Acteon Group	X-MIND TRIUM (Primary predicate)	21 CFR §892.1750 Computed tomography X-ray system	2	OAS	K160166	November 15, 2016
Midmark Corporation	Progeny Vantage Panoramic Extraoral Radiation Imaging System with Cephalometric Attachment (Secondary predicate)	21 CFR §872.1800 Extraoral source X-ray system	2	MUH	K122643	January 7, 2013

5.3 Indications for Use

The intended use of the Midmark EOIS is to provide dental radiographic examination to aid in the diagnosis of diseases of the teeth, jaw and oral structures. When the system is equipped with the cephalometric option, the system will provide cephalometric radiographic examinations for use in orthodontic treatment planning and evaluation. When the system is equipped with the CBCT option, the system will also provide volumetric and tomographic images of the oral and maxillofacial region, for diagnostic examination of teeth, jaws, oral structures, and some cranial bones.

5.4 Device Description

The Midmark Extraoral Imaging System (EOIS) is a diagnostic X-ray system using an extraoral source intended for dental radiographic examination and diagnosis of diseases for the following regions of the patient's anatomy:

- dental (teeth)
- oral and maxillofacial region (mouth and jaw)

It produces the following radiographic images:

- Panoramic (PAN) images used for diagnostic examination of dentition (teeth), jaws and oral structures.
- Cephalometric (CEPH) images of maxillofacial region and parts of the skull for CEPH examination, if equipped with the CEPH feature.
- Carpal images assisting in estimating bone-age, if equipped with the CEPH feature, and when the carpal attachment is used.

- Cone Beam Computed Tomography (CBCT) volumetric and tomographic images of the oral and maxillofacial region for diagnostic examination of dentition (teeth), jaws, oral structures, and some cranial bones, if equipped with the CBCT small or medium feature.

The main modality is limited to PAN radiographic images but can be upgraded by installing the CEPH imaging feature, allowing the device to provide CEPH radiographic images for use in orthodontic treatment planning and evaluation. This extension is also intended to allow carpal imaging to assist in estimating bone-age.

The Midmark EOIS can be upgraded by installing a 3D option allowing the device to produce computed volumetric and tomographic images of the listed above anatomy regions by computed tomographic reconstruction of the digital X-ray data. The X-ray data is captured by two dimensional images taken by exposing the patient anatomy at different angles with a cone shaped X-ray beam. Reconstruction software converts these two-dimensional images into a three-dimensional data set.

EOIS is also available with CEPH and CBCT modalities at the time of purchase. The table below shows available configurations.

System Configurations:
1. V8001, Extraoral Imaging System, Panoramic
2. V8011, Extraoral Imaging System, Panoramic and Cephalometric
3. V8101, Extraoral Imaging System, Small CBCT
4. V8111, Extraoral Imaging System, Small CBCT and Cephalometric
5. V8201, Extraoral Imaging System, Medium CBCT
6. V8211, Extraoral Imaging System, Medium CBCT and Cephalometric
Upgrade Kits:
1. V8010, Cephalometric Feature Upgrade
2. V8100, Small CBCT Feature Upgrade
3. V8200, Medium CBCT Feature Upgrade

From a clinical point of view, the Midmark EOIS can be applied for the following medical applications:

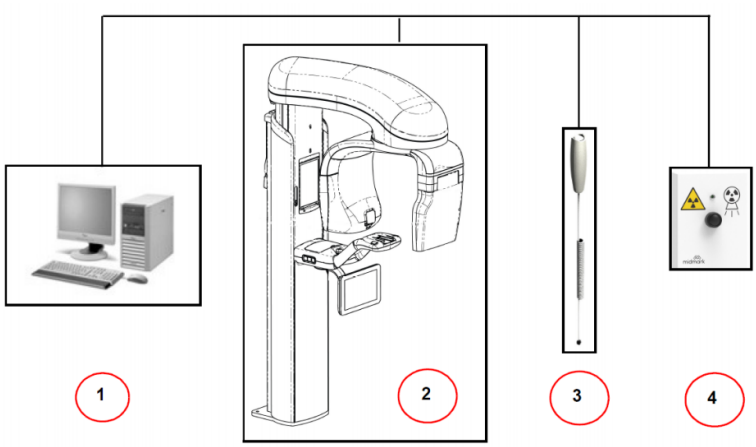
- Generic dentistry
- Dental implantology
- Dental surgery
- Maxillofacial surgery
- CEPH analysis
- Carpus radiology (for determining skeletal age)

The target patient population includes adults and pediatric patients. Joint FDA and ADA guidance describes the earliest appropriate age for panoramic imaging to be the eruption of the first permanent tooth, and FDA has indicated these guidelines also apply to CBCT imaging.

Section 5.0 510(k) Summary

The device is intended to be used by a qualified and authorized dentist or physician who meets the requirements provided by national and local laws in force in the country of installation; the operator must understand the language of the country where the device is installed.

The Midmark EOIS consists of the following components.



1 Workstation -The imaging workstation is provided for the 3D unit only. The workstation external PC allows the operator to perform these procedures:

- image visualization and post processing
- database management
- review, annotate images, and studies
- associate images and studies to patients

2 Midmark EOIS - The Midmark EOIS is a diagnostic X-ray system utilizing an extraoral source intended for dental radiographic examination and diagnosis of diseases for teeth, mouth and jaw.

3 Handswitch - The handswitch is a control connected to the cable entrance board intended to initiate and stop the X-ray irradiation when the operator remains in the vicinity of, but a safe distance from the EOIS.

4 Remote Exposure Station - The remote exposure station is a control device connected to the cable entrance board intended to initiate and stop the X-ray irradiation when the operator remains outside of the EOIS vicinity

The EOIS software is considered to be of Moderate Level of Concern and consists of the device driver and CBCT visualization software. The device driver is composed of the following subsystems:

- Reconstruction Engines take projection images consisting of radiological data and reconstructs them, resulting in a 3D dataset composed of reconstructed projection images processed using user-selectable acquisition parameters. This feature is new with the EOIS device.

  - The system offers a choice between a reconstruction based only on Filtered Back Projection (FBP) and one based on fully iterative reconstruction. The algorithm used for iterative reconstruction starts with the FBP scan data and generates projection images that it expects would be produced from the imaging of the selected volume. These images are used to evaluate the correctness of the reconstruction volume by comparing the simulated projection images to those acquired by the scanner. A metric is calculated for the correctness of the reconstructed volume and reconstruction progresses with a two-pass correction to rectify beam-hardening, scatter subtraction, and image regularization.
- Acquisition Manager provides the communications exchange between non-software subsystems and the software subsystem. It is responsible for delivering the image data from the digital sensor, through the appropriate reconstruction engine, and to the client API. In addition, it is responsible for the information relationship between the operator control panel software, real-time controller, and the connected digital sensor(s). This subsystem has been previously cleared.
- Operator Control Panel Software is used from the operator control panel to facilitate exams and service the system. It communicates with the acquisition manager software. This subsystem has been previously cleared.
- Client API provides a facility for connecting to the EOIS system and acquiring a radiological image. The Client API performs image post-processing and other tasks related to the transfer of images to an image management application. In the case of a cone beam computed tomography (CBCT) capable system, a dedicated 2D/3D visualization software application is provided (referred to as Visualization Software.) This subsystem has been previously cleared.

For an EOIS system that includes the cone beam computed tomography (CBCT) feature, dedicated visualization software is provided. This software is new to the EOIS device and facilitates acquiring exams for all supported modalities of the system. It includes a patient database, image storage, and post-acquisition image processing functionality. The software provides interoperability via an exportable DICOM (Digital Imaging Communication in Medicine) dataset.

The main differences between the EOIS device and predicate systems are the CBCT mode of operation and new digital detectors.
EOIS has three distinct image acquisition modes: Panoramic, Cephalometric and CBCT. CBCT-capable image receptors used in EOIS can take a panoramic radiograph which results in just one detector in EOIS CBCT systems with panoramic imaging and two detectors when cephalometric imaging is added.
Acteon X-Mind Trium also has three modes: Panoramic, Cephalometric and CBCT. CBCT-capable image receptors used in Acteon X-Mind Trium do not have enough vertical resolution to support a panoramic radiograph. Therefore, a separate panoramic-capable image receptor must be used, which results in Acteon X-Mind Trium having two detectors in CBCT systems with panoramic capability and three detectors in those with added cephalometric capability.
Vantage has just two modes: Panoramic and Cephalometric. Vantage does not have a CBCT mode of operation.

Section 5.5, Technological Characteristics, identifies the primary and secondary predicates and provides a comparison of technological characteristics of the EOIS with both predicates.

5.5 Technological Characteristics

Refer to the table below for a comparison of Midmark EOIS technological characteristics with those of its predicates.

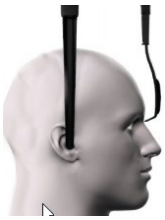
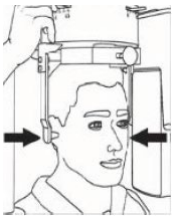
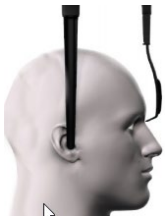
	Midmark Extraoral Imaging System (EOIS) (Subject Device)	**Acteon X-MIND Trium (Primary Predicate)**	**Vantage Panoramic X-ray System (Secondary Predicate)**
510(k) Owner	Midmark Corporation	Acteon (DE GOTZEN S.R.L)	Midmark Corporation
510(k) Number	K201667	K160166	K122643
Regulation Number	21 CFR 892.1750 21 CFR 872.1800	21 CFR 892.1750	21 CFR 872.1800
Product Code	OAS & MUH	OAS & MUH	MUH

	Midmark Extraoral Imaging System (EOIS) (Subject Device)	Acteon X-MIND Trium (Primary Predicate)	Vantage Panoramic X-ray System (Secondary Predicate)
Indications for Use	The intended use of the Midmark Extraoral Imaging System (EOIS) is to provide dental radiographic examination to aid in the diagnosis of diseases of the teeth, jaw and oral structures. When the system is equipped with the cephalometric option, the system will provide cephalometric radiographic examinations for use in orthodontic treatment planning and evaluation. When the system is equipped with the CBCT option, the system will also provide volumetric and tomographic images of the oral and maxillofacial region, for diagnostic examination of teeth, jaws, oral structures, and some cranial bones.	X-MIND Trium is a digital panoramic, cephalometric and tomographic extra-oral X-ra system, indicated for use in: - producing panoramic X-ray images for diagnostic examination of dentition (teeth), jaws and oral structures; - producing radio graphs of maxillofacial region and parts of the skull for cephalometric examination, if equipped with CEPH arm; - producing radiographs of hands and wrists for carpus examination, if equipped CEPH arm; - producing tomographic images of the oral and maxillofacial region, for diagnostic examination of dentition (teeth), jaws, oral structures and some cranial bones, if equipped, with CBCT option. From a clinical point of view, the X-MIND Trium can be applied for the following medical applications: • Generic dentistry • Dental implantology • Dental surgery • Maxillo-facial surgery • Cephalometric analysis • Carpus radiology The intended population can be whatever, including pediatric patients from 5 years old [- 21 kg (46 lb); 113 cm (44.5 in) standing height]; anyway the sustainability to X-ray exposure must be evaluated by qualified and authorized physicians, surgeons and dentists.	The intended use of the Progeny Vantage Extraoral X-Ray System is to provide dental radiographic examination and diagnosis of diseases of the teeth, jaw and oral structures. When the system is equipped with the cephalometric option, the system will also provide cephalometric radiographic examinations for use in orthodontic treatment planning and evaluation.

Section 5.0 510(k) Summary

	Midmark Extraoral Imaging System (EOIS) (Subject Device)	**Acteon X-MIND Trium (Primary Predicate)**	**Vantage Panoramic X-ray System (Secondary Predicate)**
Modalities	Panoramic Cephalometric CBCT	Panoramic Cephalometric CBCT	Panoramic Cephalometric
Technique Factor Voltage Range:			
Panoramic	60 kV to 84 kV	60 kV to 85 kV	54 kV to 84 kV
Cephalometric	60 kV to 84 kV	60 kV to 85 kV	54 kV to 84 kV
CBCT	84 kV	80-90 kV	N/A
Technique Factor Current Range:			
Panoramic	4 mA to 14 mA	4 mA to 10 mA	4 mA to 14 mA
Cephalometric	4 mA to 14 mA	4 mA to 10 mA	4 mA to 14 mA
CBCT	4 mA to 14 mA	4 mA to 12 mA	N/A
X-ray Tube Focal Spot Size	0.5 mm	0.5 mm	0.5 mm
Irradiation Time Range			
Panoramic	7.6 s to 15.9 s	3.3 s to 13.5 s	2.5 s to 16 s
Cephalometric	9.2 s to 15.6 s	3.3 s to 13.5 s	9.5 to 15.6 s
CBCT	4.7 s	4 s to 12 s	N/A
Half Value Layer:			
Panoramic	4.5 mm Al @ 85 kV	3.4 mm Al @ 85 kV	3.2 mm Al @ 85 kV
Cephalometric	4.5 mm Al @ 85 kV	3.4 mm Al @ 85 kV	3.2 mm Al @ 85 kV
CBCT	4.5 mm Al @ 85 kV	5.2 mm Al @ 90 kV	N/A
Image Receptor Technology	CMOS	CMOS	CCD
Image Receptor Scintillator	CsI	CsI	CsI
Image Receptor Active Area			
Panoramic	152 × 6.5 mm	148 × 6 mm	146 × 6 mm
Cephalometric	228 × 6.5 mm	223 × 6 mm	220 × 6 mm
CBCT	Small FOV: 147.3 × 112.0 mm; Medium FOV: 150.5 × 150.5 mm	121.6 × 123.1 mm	N/A
Image Receptor A/D Conversion (Bit Depth)	14 bits	14 bits	16 bits
Image Sizes (l x h)			
Panoramic	307 × 147 mm	260 × 148 mm	300 × 140 mm
Cephalometric	300 × 210 mm 240 × 210 mm	240 × 220 mm 240 × 180 mm 200 × 220 mm 200 × 180 mm	300 × 210 mm 240 × 210 mm
Field of View (h × w), cm	Small FOV: 5×5, 8×7 Medium FOV: 5×5, 5×8 (child), 6×8 (child), 8×8	4×4, 6×6, 8×8, 8×11	N/A
CBCT Voxel Sizes	78, 156, 195 µm	75, 100, 150 µm	N/A

Section 5.0 510(k) Summary

	Midmark Extraoral Imaging System (EOIS) (Subject Device)	**Acteon X-MIND Trium (Primary Predicate)**	**Vantage Panoramic X-ray System (Secondary Predicate)**
Patient Positioning, PAN/CBCT	Chinrest Forehead Support Bite block TMJ nose support	Chinrest Forehead support Bite block TMJ nose support	Chinrest, Positioning wands Bite block TMJ nose support
			
Patient Positioning, Ceph	Ear posts Nasion support	Ear posts Nasion support	Ear posts Nasion support
			
Laser Classification per IEC 60825-1	Class 2	Class 1M	Class 2
Laser Wavelength	650 nm	650 nm	650 nm
Laser Power	3 mW	1 mW	3 mW
Laser Diffractive Optics	Line, 40 °	Line, 90 °	Line, 40 °
Operating Temperature	5 °C to 40 °C	10 °C to 30 °C	5 °C to 40 °C
Relative Humidity (non-condensing)	5 % to 85 %	25 % to 75 %	5 % to 85 %
Atmospheric Pressure	70 kPa to 106 kPa	85 kPa to 106 kPa	70 kPa to 106 kPa
Focal Spot Target Material	Tungsten	Tungsten	Tungsten
Filter Material	Aluminum & Copper	Aluminum (Pan/Ceph) Aluminum & Copper (CBCT)	Aluminum
Image Receptor Material	CMOS with CsI	CMOS with CsI	CCD with CsI
Standards Compliance	IEC 60601-1:2005+A1:2012 IEC 60601-1-3:2013 IEC 60601-1-6:2013 IEC 60601-2-63:2017 IEC 60601-1-2:2014 IEC 61223-3-4:2000 IEC 60825-1:2014 ISO 10993-1:2018 IEC 62366-1:2015	IEC 60601-1 3rd ed ANSI/AAMI ES60601-1: 2005 IEC 60601-1-3: 2008 IEC 60601-1-6: 2010 IEC 60601-2-63: 2012 IEC 60601-1-2:2007 IEC 62366:2007 ISO 14971	IEC 60601-1:2005 IEC 60601-1-3: 2008 IEC 60601-1-6: 2010 IEC 60601-2-63: 2012 IEC 60601-1-2:2007 IEC 61223-3-4:2000 IEC 60825:2007 ISO 14971:2007 ISO 13485:2003

	Midmark Extraoral Imaging System (EOIS) (Subject Device)	Acteon X-MIND Trium (Primary Predicate)	Vantage Panoramic X-ray System (Secondary Predicate)
	ISO 14971:2007 ISO 13485:2016		

5.6 Non-clinical Performance Data

Non-clinical evaluations were performed for the EOIS. A summary of testing and results is shown in the table below.

Testing	Results
Medical electrical safety testing, including X-ray safety, electromagnetic compatibility, and usability (IEC 60601 standards)	Passed; the results of the third-party testing demonstrate compliance of the device to the standards.
Imaging performance testing (IEC 61223-3-4)	Internal verification testing was performed in accordance with IEC 61223-3-4, and all acceptance criteria were met.
Dose comparison evaluation, including predicate comparison, diagnostic reference level (DRL) comparison, and literature review.	Midmark EOIS was shown to produce similar or less radiation dosage than comparable devices on market.
CBCT modality testing, including iterative reconstruction performance, implant performance, geometric normalization, QC (DIN 6868-161), and uniform phantom performance	CBCT-related functionality performs according to specifications and produces images of acceptable quality.

5.7 Clinical Performance Data

The clinical testing performed for the EOIS consisted of a) an Image Performance study that evaluated image quality by having qualified clinicians evaluate images of phantoms and b) a usability study that examined use-related hazards with simulated use testing involving qualified clinicians.

Image Performance Study

The clinical acceptability of Midmark EOIS panoramic, cephalometric, and CBCT images was assessed by a panel of dental practitioners. Images were generated using head and

hand phantoms, provided to the clinicians and then rated for diagnostic acceptability. Results showed that all EOIS imaging protocols provided overall acceptable image quality.

Usability

The usability of the EOIS, as it relates to safety, was evaluated by 18 participants consisting of hygienists, dental assistants, and dentists. Participants were observed interfacing with the device to operate all imaging protocols and were also interviewed after. Results demonstrate that the final interface design of the EOIS facilitates safety for operators.

5.8 Conclusion

The Midmark EOIS is substantially equivalent to other legally marketed devices in the United States in terms of technical characteristics, intended use, and effectiveness; specifically, the Acteon X-MIND TRIUM system and the Progeny Vantage Panoramic X-ray System.