Pausch Medical GmbH
% Oliver Eikenberg, Ph.D.
Senior Consultant, QA & RA
EMERGO Global Consulting LLC
2500 Bee Cave Road, Building 1, Suite 300
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April 12, 2018

Re: K180651
Trade/Device Name: Uroview FD II
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA
Dated: February 23, 2018
Received: March 13, 2018

Dear Dr. Eikenberg:

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.

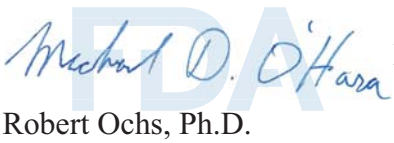
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*

K180651

Device Name
Uroview FD II

Indications for Use *(Describe)*

The Uroview FD II is a solid state detector fluoroscopic X-ray system, primarily for urological applications (functional x-ray-diagnostics, endourology and minimal invasive urology/surgery). The system, which includes a radiologic/urologic treatment table, may be used for urological treatment, planning and diagnostic procedures including but not limited to:

- Querying and retrieving patient information and /or images from other modalities.
- X-ray examination of the urogenital area (e.g. cyctoscopy, kidney, bladder, ureter, urethra) including KUB, IVP, vasovesiculography, reflux-cystogram, cystourethrogram, and micturation cystourethrogram combined with uroflow measurements.
- Ultrasound examinations (in conjunction with a stand-alone ultrasound system) of the kidney, bladder, prostate, scrotum.
- Endourological interventions (e.g. of the urethra, prostate, bladder, sphincter, ostium, kidney and ureter, catheter placement, penile implant placement, transurethral resection of prostate or bladder, alternative treatment of the BPH and brachytherapy).
- Percutaneous interventions (e.g. PCN nephrolithotomy, resection, percutaneous nephrostomy).
- Laparoscopy (e.g. cholecystectomy, nephrectomy, lymph node dissection, abdominal testis detection/correction, varicocele).
- Application of fistula (kidney/bladder).
- Simple procedures (e.g. urethra, testis, phimonis).
- Introcorporeal shock wave lithotripsy.
- Uroflow/urodynamics.
- Pediatric radiological and therapeutic applications.

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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Section 5 – 510(k) Summary

Uroview FD II

K 180651

1. Submission Sponsor

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3. Date Prepared

February, 23 2018

4. Device Identification

Trade/Proprietary Name:	Fluoroscopic, Image Intensified X-ray System
Common/Usual Name:	X-ray System
Classification Name:	Image-intensified fluoroscopic x-ray system
Regulation Number:	892.1650
Product Code:	JAA
Device Class:	Class II
Classification Panel:	Radiology
Guidance:	FORM FDA 3626 (1/14), A Guide for the Submission of Initial Reports on Diagnostic X-Ray Systems and Their Major Components

5. Legally Marketed Predicate Device

Uroview FD (K161019) from Pausch Medical GmbH, Germany

6. Device Description

The **Uroview FD II** is a solid state detector fluoroscopic, X-ray system, primarily for urological applications (functional x-ray diagnostics, endourology and minimal invasive urology/surgery). The basic unit is a cantilevered, continuously adjustable, isocentric tilting patient table called the **Uroview FD Skeleton**, which can be raised and tilted to provide convenient access for the patient as well as optimum and ergonomic operating conditions for the user. The **Uroview FD II X-ray system** is a completely mounted system and is equipped with a digital imaging system with a dynamic flat detector, designed to replace traditional spot film devices using screen-film cassettes or "CR" plates and fluoroscopy with image intensifier CCD cameras. The system is also equipped with a generator and automatic, multilayer, square field collimation system intended for installation on stationary X-ray equipment. A rotating anode X-ray tube is mounted. The measuring chamber is placed between the patient and the detector in order to detect the actual dose value for the automatic exposure control (AEC), to provide consistent x-ray film appearance and to guarantee error-free images even at low kV values. Attenuation factor is low and X-ray scattering is reduced to minimum by using a moveable grid.

The **Uroview FD II X-ray system** includes the following major components:

- Uroview FD Skeleton (urological table incl. tilting table)
- High Frequency RF X-ray generator
- X-ray tube incl. housing
- Collimator
- Measuring chamber
- Grid
- Dynamic flat panel detector
- Digital imaging workstation
- Video monitors
- Accessories

The **Uroview FD II** is considered as an update to the model Uroview FD with some new components as part of the continuous X-ray system evolution. Major X-ray components are identical to the Uroview FD and new components use FDA-cleared or FDA-registered X-ray components. Therefore the **Uroview FD II** is considered similar by properties and technological characteristics.

The **Uroview FD II** system is designed to meet the requirements in accordance with relevant sections of 21 CFR 1020.30-1020.33.

7. Indication for Use Statement

The **Uroview FD II** is a solid state detector fluoroscopic X-ray system, primarily for urological applications (functional x-ray diagnostics, endourology and minimal invasive urology/surgery). The system, which includes a radiologic/urologic treatment table, may be used for urological treatment, planning and diagnostic procedures, including but not limited to:

- Querying and retrieving patient information and/or images from other modalities
- X-ray examinations of the urogenital area (e.g. cystoscopy, kidney, bladder, ureter, urethra) including KUB, IVP, vasovesiculography, reflux-cystogram, cystourethrogram, and micturation cystourethrogram combined with uroflow measurements.
- Ultrasound examinations (in conjunction with a stand-alone ultrasound system) of the kidney, bladder, prostate, scrotum.
- Endourological interventions (e.g. of the urethra, prostate, bladder, sphincter, ostium, kidney and ureter, catheter placement, penile implant placement, transurethral resection of prostate or bladder, alternative treatment of the BPH and brachytherapy).
- Percutaneous interventions (e.g. PCN nephrolithotomy, resection, percutaneous nephrostomy)
- Laparoscopy (e.g. cholecystectomy, nephrectomy, lymph node dissection, abdominal testis detection/correction, varicocele)
- Application of fistula (kidney/bladder)
- Simple procedures (e.g. urethra, testis, phimosis)
- Intracorporeal shock wave lithotripsy
- Uroflow/urodynamics
- Pediatric radiological and therapeutic applications

8. Substantial Equivalence Discussion

The update of the model Uroview FD to the new X-ray system **Uroview FD II** is identical by technological characteristics, design and mode of operation for the components “Tube, Measuring Chamber, Anti Scatter Grid”.

The **Uroview FD II** further shares optimized component features or equivalent X-ray components to that of the predicate Uroview FD for Urological Table Uroview FD Skeleton, Generator, Digital Imaging System and Monitor beam- limiting device flat detector and digital imaging processing. The changes refer to design/size variations, image resolution, workstation functionalities and use of FDA-registered or FDA-cleared commercially available X-ray components, which are specifically designed for use in X-ray systems and therefore include standardized values and settings for electrical, mechanical and radiation requirements. As such the identified differences are considered to be optimized system variations, which are adequately controlled by testing of this X-ray system. The modifications of the **Uroview FD II** compared to the previous model Uroview FD are within the controls and predetermined specifications and are supported with verification and validation testing. The following table compares the **Uroview FD II** to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing.

The comparison chart reveals that the technological characteristics and as such the functions performed by the **Uroview FD II** offer substantially the same data and technology as the Uroview FD. The subject device is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns.

Table 5A – Comparison of Characteristics for Uroview FD II to Legally Marketed Device Uroview FD

	Proposed Device Uroview FD II	Predicate Device Uroview FD	Similarities / Differences
Manufacturer	Pausch Medical GmbH	Pausch Medical GmbH	N/A
Product/Trade Name:	Uroview FD II	Uroview FD	N/A
510(k):	Pending	K161019	N/A
Establishment Registration No.	9610903	9610903	N/A
Product Code:	JAA	JAA	Same
Regulation Number	21 CFR 892.1650	21 CFR 892.1650	Same
Device Classification	Solid State x-ray imager (flat panel/digital imager)	Solid State x-ray imager (flat panel/digital imager)	Same classification
Class	II	II	Same
Indications for use	The Uroview FD II is a solid state detector fluoroscopic X-ray system, primarily for urological applications (functional x-ray-diagnostics, endourology and minimal invasive urology/surgery). The system, which includes a radiologic/urologic treatment table, may be used for urological, treatment, planning and diagnostic procedures including but not limited to: • Querying and retrieving patient information and/or images from other modalities. • X-ray examinations of the urogenital area (e.g. cyctoscopy, kidney, bladder, ureter, urethra) including KUB, IVP, vasovesiculography, reflux-cystogram, cystourethrogram, and micturation cystourethrogram combined with uroflow measurements. • Ultrasound examinations (in conjunction with a stand-alone ultrasound system) of the kidney, bladder, prostate, scrotum. • Endourological interventions (e.g. of the urethra, prostate, bladder, sphincter, ostium, kidney and ureter, catheter placement, penile implant placement, transurethral resection of prostate or bladder, alternative treatment of the BPH and brachytherapy) • Percutaneous interventions (e.g. PCN nephrolithotomy, resection, percutaneous nephrostomy). • Laparoscopy (e.g. cholecystectomy, nephrectomy, lymph node dissection, abdominal testis detection/correction, varicocele). • Application of fistula (kidney/bladder). • Simple procedures (e.g. urethra, testis, phimosis). • Intracorporeal shock wave lithotripsy. • Uroflow/urodynamics. • Pediatric radiological and therapeutic applications		Same The intended use definition is identical except for the device name Uroview FD versus Uroview FD II
Complies with Applicable Voluntary EC, EMC-Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-3 IEC 60601-1-6 IEC 60601-2-28 IEC 60601-2-43 IEC 60601-2-54	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-3 IEC 60601-1-6 IEC 60601-2-28 IEC 60601-2-43 IEC 60601-2-54	Same
Complies with ISO 10993-1 for Biocompatibility	yes	yes	Same
Sterile:	N/A	N/A	N/A
Shelf Life (usable lifetime)	Ten years	Ten years	Same

Table 5A – Comparison of Characteristics for Uroview FD II to Legally Marketed Device Uroview FD - Continued for Technological Characteristics

	Proposed Device Uroview FD II	Predicate Device Uroview FD	Similarities / Differences
Overview of Component Specifications			
Major Components Basic Unit	1. Uroview FD Skeleton Basic Unit (urological table) 2. X-ray Generator 3. X-ray tube and housing 4. Collimator 5. Measuring chamber 6. Digital image workstation 7. Detector	1. Uroview FD Skeleton (basic unit, urological table) 2. X-ray Generator 3. X-ray tube and housing 4. Collimator 5. Measuring chamber 6. Digital image workstation 7. Detector	Same
Basic Unit (urological table)	**Uroview FD Skeleton**	**Uroview FD Skeleton**	**Similar** Newly designed with similar functionality
Basic Unit System	Optional right-handed or left-handed version	Optional right-handed or left-handed version	Same
Table height	Continuously adjustable by motor drive: 64 to 116.5 cm (25.2 to 45.9''), floating	Continuously adjustable by motor drive: 64 to 116.5 cm (25.2 to 45.9'') , floating	Same
Tabletop extensions	78 cm (30.7'') x 75.9 cm (29.9'')	78 cm (30.7'') x 75.9 cm (29.9'')	Same
Tabletop-detector distance	6.4 cm (2.5'')	6.4 cm (2.5'')	Same
Source-detector distance	115 cm (45.3'')	115 cm (45.3'')	Same
Manual / Motorized movement park position to exposure position	27 cm (10.6'') park position 27 cm (10.6'')	27 cm (10.6'')	Similar, additional park position function
Tilt range	Motorized tilt: ± 88 ° Isocentric tilt: ± 20 °	Motorized tilt: ± 88 ° Isocentric tilt: ± 20 °	Same
Tilting speed	3.5 °/s ± 0.3 °/s Isocentric tilting speed (0°-20°) 2 °/s ± 0.5 °/s	3.5 °/s ± 0.3 °/s Isocentric tilting speed (0°-20°) 2 °/s ± 0.5 °/s	Same
longitudinal movement of table top	47.75 cm (18.8'') max. 23.88 cm (9.4''), each direction Motorized, continuous travel	47.75 cm (18.8'') max. 23.88 cm (9.4''), each direction Motorized, continuous travel	Same
transversal movement of table top	14 cm (5.6'') max. 7 cm (2.8''), each direction Motorized, continuous travel	14 cm (5.6'') max. 7 cm (2.8''), each direction Motorized, continuous travel	Same
Movement Tube Unit/Flat detector, Speed of Movement	20 cm (8'') 4 ± 0.6 cm/s (1.57 ± 0.24 Inch/s) Synchronized longitudinal travel	20 cm (8'') 2 cm/s ± 0.3 cm/s (0.79 ± 0.12 Inch/s) Synchronized longitudinal travel	Similar, new designed with faster movement
Tube Assembly park position	Manual travel : 36.1 cm (14.2'')	Manual travel : 36.1 cm (14.2'')	Same
Table load	Max. 285 kg (628 lbs)	Max. 285 kg (628 lbs)	Same

Table 5A – Comparison of Characteristics for Uroview FD II to Legally Marketed Device Uroview FD - Continued for Technological Characteristics - continued

	Proposed Device Uroview FD II	Predicate Device Uroview FD	Similarities / Differences
Generator	**CPI INDICO IQ**	**Editor HFe 601**	**Similar**
Type	Microprocessor-controlled high-frequency generator for radiography and fluoroscopy	Microprocessor-controlled high-frequency generator for radiography and fluoroscopy	Same
Power	80 kW	65 kW	Similar higher power input
Radiographic kV range/steps Radiographic mA range	40 to 150 kV in 1 kV increments 10-1000 mA (20 steps), 1 mA steps, 0.1 mA steps optional	40 to 150 kV in 1 kV increments 10-500 mA (18 steps), 10-650 mA (19 steps), 10-800 mA (20 steps), 1-630 mA (38 steps). 0.5-600 mAs (32 steps)	Similar Newly features with additional steps to adjust range
Fluoroscopic kV/mA range	40-125 kV / 0.5-20.0 mA	40-125 kV / 0.5-5.0 mA	Similar Extended mA range
Active Dose Reduction (ADR)	yes	yes	Same
Automatic Exposure Control	yes	yes	Same
X-ray tube	**RAD-60 + Sapphire housing**	**RAD-60 + Sapphire housing**	**Same**
Collimator	**Optica 40**	**R225 ACS DHHS**	**Similar**
Field Type	Square Field: without potentiometer	Square Field: without potentiometer	Same
Light Source	White LED	White LED	Same
X-ray rating up	150 kVp	150 kVp	Same
Aluminium equivalent	1.2 mm AI equivalence	2 mm AI equivalence	Similar, smaller AI equivalent
Measuring Chamber	**SSMC601**	**SSMC601**	**Same**
Detector	**PaxScan 4343CB**	**Pixium RF4343 FL**	**Similar**
Type	Flat Panel Detector	Flat Panel Detector	Similar
Input fields	42.7 x 42.7 cm / 28.5 x 28.5 cm	43 x 43 cm / 30 x 30 cm / 20 x 20 cm / 15 x 15 cm	Similar, small input field differences
Pixel Pitch	139 µm	148 µm	Similar
A/D conversion	16 bits	16 bits	Same
Cooling	Ambient air flow (NO water cooling required)	Ambient air flow (NO water cooling required)	Same

Digital Imaging System	**Nexus DRF Digital (Option 1)**	**HIRIS RF43FL (Option 2)**	**HIRIS RF43FL**	**Similar for Nexus DRF Digital Same for HIRIS RF43FL**
Digital Imaging System	Fluoroscopy and radiography modes (remote control) – using a large flat panel detector	Fluoroscopy and radiography modes (remote control) – using a large flat panel detector		Similar, same flat panel detector specifications, more up to date digital imagingc features
Digital Imaging	Continuous Fluoroscopy Pulsed Fluoroscopy Radiography	Continuous Fluoroscopy Pulsed Fluoroscopy Radiography		Same
Network Interface	DICOM 3.0	DICOM 3.0		Same

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of the **Uroview FD II** that is the subject to this 510(k) submission and in showing substantial equivalence to the predicate device (**Uroview FD** K160119), Pausch Medical GmbH completed a number of non-clinical performance tests. The **Uroview FD II** meets all the requirements for overall design, biocompatibility, and electrical safety results confirming that the design output meets the design inputs and specifications for the device.

The **Uroview FD II** passed all the testing in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

- Biocompatibility testing for the **Uroview FD II** patient-contacting materials including cytotoxicity, sensitization and irritation reactivity per ISO 10993-1, 5, 10: PASSED all testing
- Electrical safety testing per IEC 60601-1: PASSED required testing
- Electrical safety testing per IEC 60601-2-2: PASSED required testing
- Electromagnetic Compatibility testing per IEC 60601-1-2: PASSED required testing
- Electromagnetic Safety testing per IEC 60601-1-6: PASSED required testing
- Electromagnetic Safety testing for X-ray tube assemblies for medical diagnosis per IEC 60601-2-28: PASSED required testing
- Electromagnetic Safety testing for X-ray equipment for interventional procedures per IEC 60601-2-43: PASSED required testing
- Electromagnetic Safety testing for X-ray equipment for radiography and radioscopy per IEC 60601-2-54: PASSED required testing
- Radiation dose documentation per IEC 61910-1: PASSED required testing
- Usability engineering testings per IEC 62366: PASSED required testing
- Software verification and validation testing has been completed on a functional level for a Moderate Level of Concern software including system compatibility testing, risk analysis and user interface testing per IEC 62304/FDA Guidance: PASSED required testing
- Shelf Life Testing for a period of ten (10) years based upon a 13000 life cycles for the **Uroview FD II** unit including testing for tube arm support, cassette box, vertical system movement, table tilt, longitudinal movement, transversal table top movement: PASSED all testing
- Packaging and Transport Testing including humidity, temperature and vibration testing for **Uroview FD II** to maintain integrity through normal shipping and handling: PASSED all testing
- Risk Management per ISO 14971 and EN ISO 14971: all requirements were met and risks reduced as far as possible.

10. Clinical Performance Data

There was no human clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate device, have been on the market for many years with proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise additional questions regarding its safety and effectiveness as compared to the predicate device(s).

It has been shown in this 510(k) submission that the difference between the **Uroview FD II** and the predicate device **Uroview FD** does not raise any questions regarding its safety and effectiveness. Technological product characteristics, performance testing and compliance with voluntary standards, demonstrate that the **Uroview FD II** device is substantially equivalent to the relevant aspects of the predicate device in terms of design, components, materials, principals of operation, performance characteristics, and intended use.

The **Uroview FD II system**, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device(s).