



Food and Drug Administration
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Pausch Medical GmbH
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August 17, 2017

Re: K161019
Trade/Device Name: Uroview FD
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA
Dated: July 04, 2016
Received: July 07, 2016

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



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

Indications for Use

510(k) Number (if known)

K161019

Device Name

Uroview FD

Indications for Use (Describe)

The Uroview FD 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. 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).
- 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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510(k) Summary

Uroview FD

K161019

1. Submission Sponsor

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3. Date Prepared

15 August 2016

4. Device Identification

Trade/Proprietary Name: Uroview FD
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

UROSOP Omnia (K101491, 06/30/2010) from Siemens Medical Solutions USA Inc.

6. Device Description

The **“Uroview FD”** 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 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 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 (Pixium RF4343 FL, originally cleared under K080859)
- Digital imaging workstation
- Video monitors
- Accessories

The Uroview FD X-ray System includes the following two software programs: HIRIS RF43 and Uroview FD software; these are explained briefly.

The Hiris RF43 software controls the digital imaging system in fluoroscopy and radiography modes using the flat panel detector. The software is specifically designed for remote controlled fluoroscopy and radiography and emergency equipment and performs real-time X-ray diagnostics of the skeleton, the gastro-intestinal tract and the urogenital system.

The Uroview FD software controls the patient table Uroview FD (Skeleton) and does not interact with the HIRIS RF43 software. It allows the user comprehensive control of the patient table via hand control and foot switch allowing operator to activate movement of the Uroview FD.

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

7. Indication for Use Statement

The “**Uroview FD**” 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, and 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
- Paediatric radiological and therapeutic applications

8. Substantial Equivalence Discussion

The following table compares the **Uroview FD** to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The **Uroview FD** shares similar X-ray components (basic table unit, generator, X-ray tube and housing, beam-limiting device flat detector, digital imaging processing) to that of the predicate UROSKOP Omnia. X-ray generation and control equipped within the **Uroview FD** system is also similar to specifications used in the UROSKOP Omnia. Many of the components used in the **Uroview FD** system are commercially available and FDA-listed or FDA-cleared X-ray components. Detailed instructions for use including safety features are included within the device labeling and design and enable the user to operate the device in a safe and effective manner. The operators are trained health care professionals familiar with X-ray examinations to be performed. The following comparison **Table 5A** of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

Table 5A – Comparison of Characteristics for *Uroview FD* versus UROSKOP Omnia

| | Proposed Device Uroview FD | Predicate Device UROSKOP Omnia | Similarities / Differences |
|---|--|--|--|
| Manufacturer | Pausch Medical GmbH | Siemens Medical Solutions USA, Inc. | N/A |
| Product/Trade Name: | Uroview FD | UROSKOP Omnia | N/A |
| 510(k): | Pending | K101491 | N/A |
| Establishment Registration No. | 9610903 | 2240869 | N/A |
| Product Code: | JAA | JAA | Same |
| Regulation Number | 892.1650 | 892.1650 | Same |
| Device Classification Name | Image-intensified fluoroscopic x-ray system | Image-intensified fluoroscopic x-ray system | Same |
| Class: | II | II | Same |
| Indications for use | <p>The Uroview FD 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:</p> <ul style="list-style-type: none"> • Querying and retrieving patient information and /or images from other modalities. • X-ray examination 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 | <p>The UROSKOP Omnia 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, gastroenterological and gynecological treatment, planning and diagnostic procedures including but not limited to:</p> <ul style="list-style-type: none"> • Querying and retrieving patient history information and /or previous diagnosis and images from other modalities. • X-ray examination 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, brachytherapy, as well as gynecological procedures requiring radiological support). • 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 | Similar, only reduced for gastroenterological and gynecological treatment applications |

**Table 5A – Comparison of Characteristics for *Uroview FD* versus UROSKOP Omnia
- Continued for Technological Characteristics**

| | Proposed Device Uroview FD | Predicate Device UROSKOP Omnia | Similarities / Differences |
|---|--|--|---|
| Major Components Basic Unit | 1. Basic Unit (urological table) 2. Detector , 3. Collimator 4. X-ray Generator 5. X-ray tube and housing 6. Measuring chamber 7. Digital image workstation | 1. Basic Unit (urological table) 2. Detector , 3. Collimator 4. X-ray Generator 5. X-ray tube and housing 6. Measuring chamber 7. Digital image workstation | Same |
| Uroview FD Basic Unit (urological table) | | | |
| Basic Unit System | Optional right-handed or left handed version | Optional right-handed or left handed version | Same |
| Tube Unit/Flat detector | Synchronized longitudinal travel: 20 cm (8") | Synchronized longitudinal travel: 15 cm (5.9") | Similar, other dimensions |
| Tilt range | Motorized tilt: +/- 88 ° Isocentric tilt: +/- 20 ° | Motorized tilt: +/- 90 ° Isocentric tilt: +/- 15 ° | Similar, other dimensions |
| Tube Assembly park position | Manual travel : 36.1 cm (14.2") | Motorized travel : 32 cm (12.6") | Similar, other dimensions |
| Source-detector distance | 115 cm (45.3 ") | 116 cm (45.7") | Similar, other dimensions |
| Tabletop-detector distance | 6.4 cm (2.5 ") | 7 cm (2.8") | Similar, other dimensions |
| Power requirements: | 1/N 115/200/208/230/240 VAC at 50 or 60 Hz | 3/PE~ 380/400/440/480 VAC (± 10%) at 50 or 60 Hz | Similar, other dimensions |
| Temperature range: | +10°C to +40°C | +15°C to +35°C | Similar, higher temperature working range |
| Relative humidity: | 20 % to 80% | 20 % to 75% | Similar, higher humidity working range |
| Barometric pressure: | 700 hPa to 1100 hPa | 700 hPa to 1060 hPa | Similar, higher pressure working range |
| Sterile: | N/A | N/A | N/A |
| Battery Operated | N/A | N/A | N/A |
| Complies with Applicable Voluntary 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 62304 IEC 62366 ISO 14971 | 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 62304 IEC 62366 ISO 14971 | Same |
| Complies with ISO 10993-1 for Biocompatibility | yes | yes | Same |
| Electrical Safety Testing Passed | Yes | yes | Same |
| Usable lifetime | Ten years | unknown | n/a |

**Table 5A – Comparison of Characteristics for *Uroview FD* versus UROSKOP Omnia
- Continued for Technological Characteristics**

| | Proposed Device Uroview FD | Predicate Device UROSKOP Omnia | Similarities / Differences |
|---|---|---|---------------------------------------|
| Uroview FD Patient table and table top | | | |
| Table top | Radiolucent carbon-fiber tabletop with foam mattress, allows controlled drainage of fluids: 120 cm (46.8 ") x 75.9 cm (29.9 ") | Radiolucent carbon-fiber tabletop with foam mattress, allows controlled drainage of fluids: 115 cm (45.3 ") x 76 cm (29.9 ") | Similar, other dimensions |
| Tabletop extensions | 78 cm (30.7 ") x 75.9 cm (29.9 ") | 95 cm (37.4 ")x 76 cm (29.9 ") | Similar, other dimensions |
| Height adjustable table top | Continuously adjustable by motor drive: 64 cm to 116 cm (25.2" to 45.7") , floating | Continuously adjustable by motor drive: 72 cm to 122 cm (28.3" to 48 ") floating | Similar, other dimensions |
| Longitudinal movement | Motorized, continuous travel: +/- 18.8 cm (7.9") | Motorized, continuous travel: +/-20 cm (7.9") | Similar, other dimensions |
| Transverse movement | Motorized, continuous travel: +/- 7.1 cm (2.8") | Motorized, continuous travel: +/-12.5 cm (4.9") | Similar, other dimensions |
| Table load | Max. 285 kg (628 lbs) | Max. 272 kg (600 lbs) | Similar |
| Display support arm | Spring-articulated arm mounted on the basic unit with 2 x 19" TFT color displays | Spring-articulated arm mounted on the basic unit with 2 x 19" TFT color displays | Same |
| TFT color display | Size 24" Image Matrix 1900 x 1200 Maximum brightness 600 cd/m ² | Size 19" Image Matrix 1280 x 1024 Maximum brightness 280 cd/m ² | Similar |
| Flat detector | | | |
| 43cm x 43cm | High-resolution 2840 x 2880 matrix with 148 µm pixel size and 16-bit digitization depth | High-resolution 2840 x 2880 matrix with 148 µm pixel size and 16-bit digitization depth | Same |
| Input fields | 42 x 42 cm / 30 x 30 cm / 20 x 20 cm / 15 x 15 cm | 42 x 42 cm / 30 x 30 cm / 22 x 22 cm / 15 x 15 cm | Similar |
| Material | aSi with CsI scintillator | aSi with CsI scintillator | Same |
| Pixel size | 148 µm | 148 µm | Same |
| Generator | | | |
| Description | Microprocessor-controlled high-frequency generator for radiography and fluoroscopy | Microprocessor-controlled high-frequency generator for radiography and fluoroscopy | Same |
| Power | 65 kW (650 mA at 100 kV) | 65 kW (650 mA at 100 kV) | Same |
| Exposure voltage | 40 kV to 150 kV | 40 kV to 150 kV | Same |
| X-ray tube | | | |
| Nominal voltage | 150 kV | 150 kV | Same |
| Nominal output | 40/80 kW | 40/80 kW | Same |
| Focal spot nominal value | 0.6/1.2 | 0.6/1.0 | Similar |
| X-ray tube assembly | Dual focus | Dual focus | Same |
| collimator | Automatic | Automatic | Same |
| Digital Imaging System | | | |
| 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 |

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of the **Uroview FD** and in showing substantial equivalence to the predicate device that is subject to this 510(k) submission, Pausch Medical GmbH completed a number of non-clinical performance tests. The **Uroview FD** 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** 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** 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** unit including testings 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** to maintain integrity through normal shipping and handling: PASSED all testing
- Risk Management per 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 devices, 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** and the predicate device UROSKOP Omnia 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** 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 system**, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device(s).