December 21, 2021

SRS Medical
Lee Brody
CEO
76 Treble Cove Road, Building #3
North Billerica, MA 01862

Re: K212830
Trade/Device Name: CT3000Pro
Regulation Number: 21 CFR§ 876.1620
Regulation Name: Urodynamics Measurement System
Regulatory Class: II
Product Code: FEN, EXQ
Dated: November 22, 2021
Received: November 23, 2021

Dear Lee Brody:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica K. Nguyen, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212830

Device Name
CT3000Pro

Indications for Use *(Describe)*
The CT3000Pro is intended for urodynamic testing. The equipment performs standard tests including uroflowmeter, cystometry, micturition, electromyography and urethral pressure profiles. The non-invasive option utilizes a penile cuff (UroCuff-Classic or UroCuff-DC) for non-invasive testing of bladder activity, by assessing the pressure necessary to interrupt urine flow.
The CT3000Pro is intended for use under the direction of a licensed physician or health care professional in an office or hospital setting.

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

1. Submitter:

Company:	SRS Medical 76 Treble Cove Road, Building #3 North Billerica, MA 01862
Contract Person:	Lee Brody - CEO Telephone: 978-663-2800 Fax: 425-882-1935 Email: brody@srsmedical.com
Date Prepared:	December 17, 2021

2. Device:

Trade Name:	CT3000Pro
Common/Usual Name:	Urodynamics measurement system
Classification Name:	Urodynamics measurement system
Regulation Number:	21 CFR 876.1620
Product Codes:	FEN, EXQ
Regulatory Class:	Class II
Panel:	Gastroenterology/Urology

3. Predicate Device:

Laborie Urodynamics System with Tetra, Product Code FEN, EXQ; cleared under K073552.
The predicate device has not been subjected to a design-related recall.

4. Device Description:

The CT3000Pro system is an urodynamics testing system which combines an all-in-one touch-screen PC with the CT3000Pro console. Patient information and all data from the tests are stored on the PC's hard disk and the printer enables the user to print a hard copy report of the recorded data. It features a scale to record urine flow, as well as a pump for cystometrogram and urethral pressure profile studies.

The CT3000Pro PC software runs three types of tests: (a) catheterized urodynamics, (b) non- invasive

urodynamics, and (c) uroflow studies. A brief overview of the three test procedures is given below:

a. For catheterized urodynamics studies, the device has up to three pressure channels which record pressure from one or two catheters (Vesical and optionally Abdominal). Perianal surface electromyography (EMG) can be recorded. The CT3000Pro also has a remote control and an electronic leak point detector for recording events.

b. For non-invasive urodynamics studies, the device utilizes a non-invasive UroCuff to apply pressure to the urine stream to determine the pressure required to interrupt the urine flow during a voiding pressure study. Perianal and/or Abdominal surface EMG can be recorded.

c. For uroflow studies, the device utilizes the urine scale, which is used on voiding pressure studies as well.

5. Indications for Use:

The CT3000Pro is intended for urodynamic testing. The equipment performs standard tests including uroflowmeter, cystometry, micturition, electromyography and urethral pressure profiles. The non-invasive option utilizes a penile cuff (UroCuff-Classic or UroCuff-DC) for non-invasive testing of bladder activity, by assessing the pressure necessary to interrupt urine flow.
The CT3000Pro is intended for use under the direction of a licensed physician or health care professional in an office or hospital setting.

6. Comparison of Technological Characteristics with Predicate Device:

Characteristic	Predicate Device (Laborie Urodynamics K073552)	CT3000Pro
Indications for Use	Laborie Urodynamic systems are intended for Urodynamic testing. The traditional equipment performs standard tests including uroflowmeter, cystometry, micturition, electromyography and urethral pressure profiles. The accessory to our standard equipment, Tetra near infrared spectroscopy, for non-invasive testing of bladder activity, aiding in the diagnosis of patients with lower urinary tract symptoms - that is patients who suffer from urinary incontinence. All Urodynamic equipment including the Laborie Urodynamic system with Tetra Accessory are for use under the direction of a licensed physician or health care professional in an office or hospital setting.	The CT3000Pro is intended for urodynamic testing. The equipment performs standard tests including uroflowmeter, cystometry, micturition, electromyography and urethral pressure profiles. The non-invasive option utilizes a penile cuff (UroCuff-Classic or UroCuff-DC) for non-invasive testing of bladder activity, by assessing the pressure necessary to interrupt urine flow. The CT3000Pro is intended for use under the direction of a licensed physician or health care professional in an office or hospital setting.
Use Environment	Office or hospital setting.	**Same**
Patient Population	Patients who suffer from Urinary Incontinence and other lower urinary tract symptoms.	**Same**
Users	Licensed physician or health care professional	**Same**
Catheterized Urodynamics Test Types	Uroflometry, cystometry, micturition, electromyography, and urethral pressure profiles.	**Same**
Catheterized Urodynamics Test Technique	Traditional Catheters, infusion pump, scale.	**Same**

Non-invasive Urodynamics Test Technique	Non-invasive testing of bladder activity using Near infrared spectroscopy.	Non-invasive testing of bladder activity using penile cuff.
Uroflow Test Technique	Urine Scale	**Same**
Surface EMG Technique	Standard disposable EMG electrodes. One Channel to record the electrical activity of the muscles associated with urination.	Standard disposable EMG electrodes. Two Channels to record the electrical activity of the muscles associated with urination.
Communication	Direct connection to the PC via USB cable	**Same**
Data Storage	Local PC	**Same**
System Components	Instrument console, personal computer, scale, pump.	**Same**
Electromechanical Characteristics		
Electrical Classification	Class I Equipment Type BE Applied Parts	**Same**
Degree of Protection Against Ingress of Water	IPXO Equipment	**Same**
Mode of Operation	Continuous	**Same**
Uroflow Rate	0 - 50 ml/s	**Same**
Uroflow Volume	0 - 1100 ml	0 – 1500 ml
Pressure	-40 to 350 cmH_2O	0 to 215 cmH_2O
EMG	-225 - 225 uV; Frequency: 2 to 800 Hz	225 uV; Frequency: 20-500Hz
Pump	5 to 140 ml/min	0 – 100 ml/min
Infusion	0 - 1000 ml	**Same**
T-Doc	-68 to 408 cmH_2O	**Same**

As evidenced by the above table, the subject and predicate device have different technological characteristics. Both the subject and the predicate devices are intended for urodynamic testing under the direction of a licensed physician or health care professional in an office or hospital setting. Both devices use traditional equipment to perform standard tests including uroflowmetry, cystometry, micturition, electromyography and urethral pressure profiles. Both devices also perform non-invasive testing of bladder activity. Therefore, the subject and predicate device have the same intended use.

The main differences between the devices are: (a) the CT3000Pro has an optional second surface EMG channel, (b) the CT3000Pro utilizes a penile cuff for non-invasive measurements while the predicate utilized an indirect measurement technique. There are also some differences in the device hardware specifications. However, these differences do not raise different questions of safety or effectiveness and the testing mentioned below showed that the subject is substantially equivalent with the predicate.

7. Performance Data:

Performance Data – Bench

CT3000Pro was subjected to verification and validation activities utilizing various methods and techniques to verify device performance including:

- Device Verification and Validation testing (comprehensive end-to-end testing of functional requirements).

- Full functional test performed on 100% of units as part of the final test during production release.
- Product life and durability testing.

Biocompatibility testing

1. The CT3000Pro console and associated components and accessories manufactured by SRS Medical or third-party suppliers are non-contact parts, therefore, have no biocompatibility considerations.
2. The CT3000Pro system requires patient-contacting components for some of the tests, such as catheterized urodynamics test or non-invasive urodynamics test. Except the UroCuff-DC component all the other patient-contacting components are purchased from third party manufacturers and those components are FDA registered and used with the CT3000Pro system without modifications.
3. Biocompatibility evaluation for the patient-contacting material of the UroCuff-DC was conducted in accordance with FDA's guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The material met the requirements.

Electrical safety and electromagnetic compatibility (EMC)

CT3000Pro was evaluated by a third-party certified laboratory for Electromagnetic Compatibility (EMC) and Electrical Safety. The subject device met the following standards:

- IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2 General requirements for safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.
- IEC 60601-1:2005 + A1:2012 Medical electrical equipment – Part 1: General requirements for safety and essential performance

Software Verification and Validation

The CT3000Pro software was developed, validated, and documented in accordance with IEC 62304 and FDA Guidance "General Principles of Software Validation." Software verification and validation activities including code reviews, design reviews, evaluations, analyses, traceability assessment, and manual testing were performed in accordance with standards and guidance documents to demonstrate device performance and functionality. All tests met the required acceptance criteria.

Risk Management

Risk Management activities were conducted in accordance with ISO 14971 to assure that all risk related to invasive and non-invasive urodynamic testing, including use related risks and cybersecurity risks, are appropriately controlled. All control measures were verified and found to be effective. All individual and overall residual risk is acceptable. The new device has the same safety characteristics as the Predicate Device and same risk profile.

Clinical Data

Clinical performance of the non-invasive uroflow measurement technique is demonstrated through clinical data from published literature. The use of UroCuff for non-invasive urodynamic studies has been evaluated by independent research teams and published in peer-reviewed literature. There have

been 28 Original Research Articles published on UroCuff, as well as an additional 44 Original Research Abstracts, and 20 Technology Assessments, Clinical Guidelines and Review Articles. Specifically, a study on the use of UroCuff-Classic and UroCuff-DC using the CT3000Pro (and its predecessor CT3000Plus) supporting the safety and effectiveness was published in the Journal of Urology. This publication reports on the clinical experiences on over 50,000 UroCuff patients from 103 US hospitals and urology offices. The publication's authors practice at Mayo Clinic, Mount Sinai Hospital, and Chesapeake Urology. Each of these institutions utilizes UroCuff. From the literature data it was established that the effectiveness and safety profile of the subject device are acceptable.

8. Conclusion:

Based on the information presented in this submission, it can be concluded that the subject device is substantially equivalent to the predicate.