K960503

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510(k) Summary of Safety and Effectiveness

This summary of 510(k) Safety and Effectiveness information is being submitted in accordance with the requirement of SMDA 1990 and 21 CFR § 807.92

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Device:

Trade/Proprietary Name:	Dantec Duet™
Common/Usual Name:	Urodynamics System
Classification Name:	Urodynamics Measurement System

Predicate Device

Sponsor	Product	510(k) No.
DANTEC	Menuet™	K912701
LifeTech	Janus	K904386
Wiest	Jupiter	K860571
Synectics	PolyUro	K924383

Device Description: The Dantec Duet™ is a computerized urodynamics measurement system. The system consists of a mobile cart or "trolley" with the following components mounted on it: a 486 based computer, color monitor, printer, dedicated keyboard, digital and analog measurement electronics, Windows™ based application software, transducers for measuring EMG, pressure, flow and weight, infusion stand, puller with arm, CO_2 gas pump, water pump, patient interface module and patient connecting accessories.

Intended Use: The Dantec Duet™ system is intended for urodynamics testing. The Duet™ system is intended to assist practitioners in executing specific urodynamics test protocols, collecting data during protocol execution, analyzing collected data, preparing written reports and archiving patient and testing information.

General indications for use include use in patients with lower urinary tract voiding or continence problems, and more specifically incontinent patients, patients with bladder outlet obstructions, patients with neurogenic bladder dysfunction and some children with complex voiding / incontinence problems.

Technological Characteristics:

These urodynamic systems are recorders of electrical signals from input devices connected to patients during the execution of urodynamics test protocols. In addition to data recording from electrical input devices, each system may consist of one or more accessory devices required to execute certain urological test protocols. Accessory devices typically include a puller mechanism, water pump and gas pump. (e.g., an H_2O pump for infusion of water or saline during Water Cystometry, a CO_2 pump for infusing gas during bladder testing, a puller mechanism for use during a urethral pressure measurement.)

Signal processing is performed by the system. Data acquisition is accomplished through a series of isolated inputs including: DC channels, EMG Channels, flow transducer channels, and pressure transducer channels.

The system electronics connect to the patient interfacing devices. Flow, pressure and weight transducers are connected to the transducer inputs. Electrode cables are connected to the EMG channels. Transducers and electrode cables are connected to the patient via disposable or sterilizable catheters, needle electrodes and surface electrodes. The gas and water pumps connect to the patient via catheters. The puller mechanism connects to patient catheters and is controlled by the system.

Software allows the user to control data acquisition and system accessories. The software and hardware act together to aid the clinician in performing Uroflowmetry, Urethral Pressure Measurement, Water Cystometry, Voiding Cystometry and Gas Cystometry.

Once data is collected, each system allows for review of patient information on a computer screen and the production of reports from the data collected during protocol execution. Reports may contain raw and analyzed data generally consisting of waveform and statistical information printed in chart, graphic or tabular format. Each system is capable of storing patient data for archival and later analysis.

Non Clinical Testing:

The DANTEC Duet™ was developed and validated according to written validation procedures. Substantial equivalence is based on a comparison of intended use, labeling, and specifications between the Duet™ and the predicate devices. Specifications were confirmed by in house validation and augmented by EMC and ESD testing performed by qualified testing laboratories.

Conclusion:

The Dantec Duet™ was developed and validated in accordance with the company's development procedures. System testing and validation demonstrate that the device meets the requirements of internationally recognized standards, meets its published specifications, performs as well or better than the currently marketed product and is safe and effective for its intended use.