

MAR 21 1997


ANDROMEDA

K964522

SUMMARY OF SAFETY AND EFFECTIVENESS

MANUFACTURER IDENTIFICATION:	ANDROMEDA medizinische Systeme GmbH Wallbergstrasse 5 D-82024 Taufkirchen / Potzham Germany
SPONSOR IDENTIFICATION:	Same
ESTABLISHMENT REGISTRATION NUMBER:	In process (Submitted Nov. 5, 1996)
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DATE OF PREPARATION OF THIS SUMMARY:	March 21, 1997
TRADE NAME:	<i>Ellipse 4™</i>
COMMON NAME:	Urodynamic System
CLASSIFICATION NAME:	Urodynamic Measuring System
REFERENCE:	(21 CFR Section 876.1620)
PROPOSED REGULATORY CLASS:	Class II
DEVICE PRODUCT CODE:	FAP
PANEL CODE:	GU

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DESCRIPTION OF DEVICE:

The *Ellipse 4™* is a small, compact device that can register pressures, uroflow and EMG from the patient. The signals are AD converted and displayed on a LCD screen, printed on a thermal printer and stored in memory. After the recording, the data can be copied on a printer or downloaded to a PC using a network. The *Ellipse 4™* uses microcup catheters (MTC's) for recording the pressures, and surface electrodes.

INTENDED USE:

The *Ellipse 4™* is intended to assist in the diagnosis of incontinence and/or voiding disorders.

INDICATIONS FOR USE:

The *Ellipse 4™* is a Urodynamic System. It can perform the following tests: Flowmetry, Cystometry, Pressure Flow, Urethral Pressure Profile and EMG.

PREDICATE DEVICE:

The *Ellipse 4™* is substantially equivalent to the **MERKUR™ 4000**, manufactured by F. M. Wiest Medizintechnik (K920575) and to the **SPACE™ 7500** manufactured by F. M. Wiest (K 912071).

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

Both the *Ellipse 4™* and the **MERKUR™ 4000** have the same intended use and are of very similar design. They both have a coated aluminum housing and are powered similarly. Neither deliver energy to the patient. The *Ellipse 4™* is also capable of carrying out CC-EMG investigations.

SUMMARY OF STUDIES:

Bench testing was performed to confirm accuracy of the basic parameters measured by the *Ellipse 4™*. Tests were performed in the following areas: transducer, pump, EMG, pressure, pressure flow and urethral pressure profile. Satisfactory results were achieved.

Clinical experience in use of the *Ellipse 4™* has confirmed its safety and effectiveness. Over 10,000 Urodynamic investigations have been performed using the *Ellipse 4™* with excellent results and an absence of complications.