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K971913

ALBYN MEDICAL

19 September 1997

SEP 19 1997

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Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ 401)
9200 Corporate Boulevard
Rockville
Maryland 20850
USA

Attn: Ms Nicole I. Wolanski

Dear Ms Wolanski

Re: 510(k) number K971913
GR100F Urine Flowmeter
Dated: May 14, 1997
Received: May 22, 1997

The Safe Medical Devices Act of 1990 - 510(k) Summary

(1)	Submitter's name:	Albyn Medical Ltd
	Submitter's address:	Bridgend Road Industrial Estate Dingwall IV15 9QF Scotland UK
	Submitter's tel. no:	011 44 134 986 2388
	Contact person:	Ross K. Maxwell
	Date Summary Prepared:	19 September 1997
(2)	Name of device:	GR100FS Urine Flowmeter

(3) Identification of legally marketed device to which equivalence is claimed:
Browne Medical Systems Inc "UroFlo"

(4) Description of the device.

Urine flowrate meter used for determining urine flow rate from patients performing normal micturition. The device functions by weighing the voided urine, the weight in grams approximates to the volume in ml the specific gravity of urine varies between 1.002 and 1.006 in infants and 1.010 and 1.025 in adults (95% ranges) and any inaccuracy is therefore no more than 2.5%. The urine is weighed as the urine flows using a strain-gauged load cell, the signal output from which is digitised. The flow volume is

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differentiated digitally to give the flow rate, which is printed on a paper chart recorder. The flowmeter uses algorithms to calculate the following parameters:

Total voided volume
Volume at maximum flow
Maximum flow rate
Mean flow rate
Flow time
Time of maximum flow

The recorder is a table-top device connected to the load cell which supports a jug and which fits under either a commode chair or stand.

(5) Intended use for the device

The device is intended to be used to measure urinary flow rates

(6) The device has the same technolgical characteristics as the predicate device identified in paragraph (3).

Prepared by:

Ross K. Maxwell
19 September 1997

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 19 1997

Ross K. Maxwell, Ph.D.
Director Responsible for Regulatory Affairs
Albyn Medical Ltd.
Bridgend Road Industrial Estate,
Dingwall,
Ross-shire 1V15 9QF,
SCOTLAND

Re: K971913
GR100F Urine Flowmeter
Dated: June 27, 1997
Received: July 1, 1997
Regulatory class: II
21 CFR §876.1800/Product code: 78 EXY & EXS

Dear Dr. Maxwell:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (If known): K971913

Device Name: GR100FS URINE FLOWMETER

Indications For Use:

The GR100FS is intended to be used to measure urinary flow rates.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R Sattler

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number 971913

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)