K042943

SECTION 5

510(k) SUMMARY

Submitter:	NOUVAG AG St. Gallerstrasse 23-25 CH-9403 Goldach Switzerland
Contact Person:	Benno Frei Technical Director, New Product Development Phone +41 (0)71 846 66 00 Fax +41 (0)71 845 35 36
Date Summary Prepared:	October 22, 2004
Device Name:	
Proprietary Name	Vacuson 40 and Vacuson 60
Common Name	Powered suction pump
Classification Name	Pump, Portable, Aspiration (Manual or Powered) (per 21 CFR section 878.4780)

Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:

Medela AG
Medela "Basic 30" and "Dominant 50" Suction Pumps
K021368, Cleared on 05/15/2002

Device Description:

Every model has at least one suction jar with overflow safety device, bacterial filter and optional a castered trolley. The optional foot switch can be used to activate the suction pump. The pump power can be continuously regulated by a valve and monitored through the manometer.
Vacuson 40 and Vacuson 60 are different in the maximum suction flow rate.

The Vacuson 40 has a built-in piston pump with the name "P40". The maximum suction flow rate for the Vacuson 40 Device is specified with 40 litres/min.

The Vacuson 60 has a built-in piston pump with the name "P70". The maximum suction flow rate for the Vacuson 60 Device is specified with 60 litres/min.

Sterility:
Suction tube, Suction jars with jar lids: Sterility by user up to 134°C.

Intended use of the Devices:

The Vacuson 40 and Vacuson 60 are intended as extraction suction units for vacuum extraction, aspiration and removal of fluids, and infectious material from wounds or tissue either during surgery or at the patient 's bedside.

Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device:

The Vacuson 40 and Vacuson 60 are substantially equivalent to other legally marketed devices in the United States. The Vacuson 40 and Vacuson 60 function in a manner similar and are intended for the same use as the Devices designed by Medela AG.

Brief summary of nonclinical tests and results:

The Vacuson 40 and Vacuson 60 have been designed and tested to applicable safety standards. The Vacuson 40 and Vacuson 60 do not raise any new issues of safety, effectivness, or performance of the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2004

Nouvag AG
c/o Mr. Erich Forster
INTRATest Systems GmbH
St. Gallerstrasse 23-25
CH-9403 Goldach
Switzerland

Re: K042943
Trade/Device Name: Vacuson 40 and Vacuson 60
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: II
Product Code: BTA
Dated: October 22, 2004
Received: October 25, 2004

Dear Mr. Forster:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042943

Device Name: Vacuson 40 and Vacuson 60

Indications For Use:

The Vacuson 40 and Vacuson 60 are intended as extraction suction units for vacuum extraction, aspiration and removal of fluids, and infectious material from wounds or tissue either during surgery or at the patient's bedside.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042943