DurQ
MACHINERY CORP.
聖傑機器工業股份有限公司
台中縣神岡鄉中山路1448號
NO. 1448, CHUNG SAN RD.,
SHEN KANG HSIANG, TAICHUNG, TAIWAN, R.O.C.
TEL 886-4-2561-3111 FAX 886-4-2561-3589
URL http://www.durq.com.tw
E-MAIL durq@tcts.seed.net.tw

2-1

JAN 1 8 2002

K013116

510(k) Summary

(1) Submitter's Name:

Durq Machinery Corp.

Address

No. 1448, Chung San Rd., Shen Kang Hsiang, Taichung,Taiwan, R.O.C

Phone: 886-4-2561-3111 Fax: 886-4-2561-3589

Contact : Ray Liao/ R&D Engineer

Summary Prepared Date: Aug. 29, 2001

(2) Trade Name and Products

Trade name 1. - Durq

Trade name 2. -QualiDura

Product - Electric Nose Vacuum (Aspirator)

Model No : 02001

Classification name – BTA Powered Pump Aspiration (per 21 CFR section \ 878.4780)

(3) Reason of Submission:

A New Device.

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2-2

(4) Description of the device

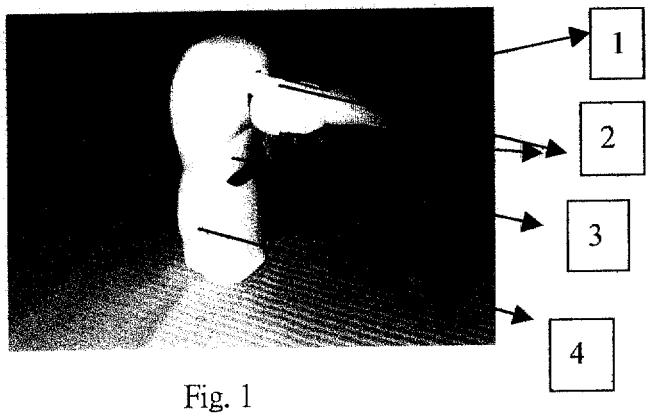

Fig. 1

1. Material: Silicone Rubber
   Manufacturer: Silastic
   Cat. No. : K770
   FDA: 21 CFR177.2600

2. Collection Cup
   Material: PC
   Manufacturer: Lexan
   Cat. No. : 144R
   FDA: 21 CFR177.2600

3. Button:
   Material: TPR
   Manufacturer: Sarlink
   Cat. No. : 3170
   FDA: 21 CFR 177.2600

4. Enclosure:
   Material: ABS
   Manufacturer: Chi Mei Corp.,

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(5) Intended use of the device [807.92(a)(5)].

It is designed to improve the disadvantages of the conventional rubber bulb type aspirators with poor suction power , unstable and hard to use. Now no more squeezing by hands or suction by mouth. It removes nasal mucus and fluids from baby's nostrils at home safely and easily.

(6) Per section 807.92(a)(6), the 510(k) claiming equivalence.

N/A

(7)Substantial equivalence [807.92(b)(1)].

N/A

(8) Substantial equivalence [807.92(b)(2)].

N/A

(9) Per section 807.92(b)(3)

N/A

(10) Safety

Power:

4.5 V DC Power Supply (without electric shock hazard.)

Vacuum Pressure:

0- 45 kpa (without person injury hazard.)

Contact Nozzle Material :

Silicone Rubber, Cat. No. : K770 by Silastic, are listed in 21CFR177.2600(without poisoned hazard.)

Warning Labeling :

See 3-22 .

Warning provided in Instruction:

See OPERATION MANUAL.

Ref:

5. PERSONAL HYGIENE AND HEALTH CARE APPLIANCES

UL 1431 Check List

DurQ
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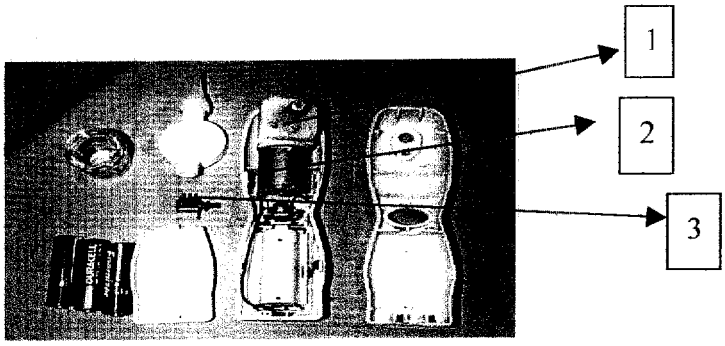

Fig. 2

1. Pump Body
   Material: POM
   Manufacturer: Polyplastics Co., Ltd.,
   Cat. No. : M90-01
   FDA: 21 CR 177.2470

2. DC Motor
   Manufacturer: Mabuchi Motor Co., Ltd.,
   Cat. No. : RE-280SA-2865
   Operating Voltage: 1.5 V – 4.5 V DC
   Nominal Voltage: 3 V - 4.5 V DC

3. DC Momentary Start Switch
   Manufacturer: Sweeta Products Corporation
   Cat. No. : PS-22F05
   Rating: 50 V DC 0.3 A
   Operation: Push start(momentary contact).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 8 2002

Mr. Daniel Yang
Ever-Safety Technical Service
No. 13, Alley 28, Lane 108
Young Feng Road
Taichung Hsien, Taiwan
China

Re: K013116
Trade/Device Name: Dura/QualiDura
Regulation Number: 878.4780
Regulation Name: Powered suction pump
Regulatory Class: II
Product Code: BTA
Dated: December 17, 2001
Received: December 27, 2001

Dear Mr. Yang:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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 Mark N Melkerson

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

510(k) Number (if known): K013116

Device Name: Electric Nose Vacuum

Indications For Use:

THE ELECTRIC NOSE VACUUM IS DESIGNED TO REMOVE NASAL MUCUS AND FLUIDS FROM BABY'S NOSTRILS.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)

for Mark N. Melkerson

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

510(k) Number K013116