AUG -7 1998

K973705

Tab 13

Summary

contOR® Table Surface

Hill-Rom®
A HILLENBRAND INDUSTRY

Tab 13

510(k) Summary
contOR® Table Surface

Date Prepared: 9-26-97

1. SUBMITTER NAMES:

Submitter:
Hill-Rom®
4349 Corporate Road
Charleston SC 29405

Contact:
Edwin Bills
Manager Quality Services & Regulatory Affairs
4349 Corporate Road
Charleston SC 29405
(803)740-8380
FAX: (803)740-8059

2. DEVICE NAMES:

Common or Usual or Classification Name: Specialty Mattresses for use on Operating Room Tables and Patient Stretchers

Proprietary Name: contOR® Table Surface

3. PREDICATE DEVICES:

Surface

Action Gel Pad manufactured by Action Products, Inc. Hagerstown, MD
AMSCO Operating Room Table Pad, AMSCO International, Erie, Pa.
Olympic VAC-Pac manufactured by Olympic Medical, Seattle, WA

Hyper- Hypothermia Pad/Blanket and Controls

Blanketrol II manufactured by Cincinnati Sub-Zero, Cincinnati, OH
TROPI-Cool Hyper/Hypothermia manufactured by Seabrook Medical, Cincinnati, OH

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4. SUBJECT DEVICE:

a) Control Unit

The control unit is a self-contained unit requiring only input of the local power system. The control unit contains the heat exchanger used to heat/cool the medium. In addition, the control unit contains a pressure/vacuum pump and valve network for inflating the positioning air bladders and deflating the beaded vacuum bags. The control unit also contains all the controls required to manipulate and monitor the previously mentioned subsystems as well as any other subsystems that might be required for the patient and/or table surface pad while being used in the O. R. Suite. The control unit, which utilizes membrane switch technology and LED screen display the functions of the contOR® Table Surface. Additionally there is a remote pendant that is wired to the control unit that performs the same functions as the main control unit's screen.

b) Mattress Set

The mattress set of the contOR® Table Surface Unit is designed to be used on different operating room tables in lieu of the standard mattress set. The mattress is 21 inches wide, 72 to 84 inches long and 4 inches high. All aspects of the OR table surface pad are as modular in design as possible to facilitate serviceability and repair. The OR surface pad consists of 3 sections; a head section, a main body section, and a foot/leg section. The OR surface pad is a multi-ply system contained in an outer cover. The outer cover material has bi-directional stretch and is a nylon web substrate with urethane laminated on both sides. This outer cover will be cleanable throughout the life of the product using standard Hospital disinfectants that are alcohol or phosphate detergent based. The multi-ply system contained in the outer cover consists of several different layers.

The contOR® Table Surface pads are interconnected using Colder fittings for air, vacuum and water supply. Each section is secured to the OR table by longitudinal Velcro strips placed down the center of the under surface each section.

5. INDICATIONS FOR USE:

The contOR® Table Surface is intended to be used on existing operating room table in all surgical procedures to greatly reduce the likelihood of complications as a result of placement on the operating table surface, such as:

- **pressure ulcers (pressure relief)**
- **tissue compromise (positioning)**

6. COMPARISON TO PREDICATES:

Differences in design between the subject device and the predicates (none of which have significant effect on safety and efficacy) are as follows:

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Mattress Set

a) **The contOR® Table Surface Incorporates numerous layers, each of which is similar to a predicate. The predicate devices exist as single units.**

b) **The range of the thermal pad is from 39 degrees F to 104 degrees F in the contOR® Table Surface and from 39 degrees F to 107 degrees F for the stand alone thermal. Unit.**

(See Tab 8: Comparison Chart for further comparisons.)

7. **SUMMARY**:

The functions of the contOR® Table Surface Unit and the predicate devices are designed for:

a) **the prevention and treatment of pressure ulcers through pressure reduction/relief;**

b) **any use where benefits may be derived from warming/cooling the patient;**

c) **the position assistance/protection of the patient to reduce the risk of tissue compromise.**

The c ontOR Table Surface® Unit is able to accomplish these functions through the operation of the specially coordinated steps performed by an OR staff member in selected combinations which are configured and controller through resident software in the controller.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 7 1998

Mr. Edwin L. Bills
Official Correspondent
Hill-Rom, Inc.
4349 Corporate Road
Charleston, South Carolina 29405-7445

Re: K973705
contOR® Table Surface
Regulatory Class: II
Product Code: DWJ
Dated: April 8, 1998
Received: May 20, 1998

Dear Mr. Bills:

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) 594-4659. 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" (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,

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

Enclosure

510(k) Number:

contOR® Table Surface

Indications for Use:

The contOR® Table Surface is intended to be used to support and position the patient and to provide warming and cooling during surgery. The surface will reduce the likelihood of complications as a result of placement on the operating table surface such as:

- Pressure ulcers
- Tissue compromise

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use ____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973795