

FEB 16 2000



K993872

510k Summary

The safety and usefulness of the VÄNNA Bathing System is based on a long history of use of hydro-baths with similar characteristics. As referred to previously the VÄNNA Bathing System uses similar technology and components as other devices already on the market. Technological updates have been used in the VÄNNA Bathing System in the temperature sensor and temperature read-out indicators but these differences enhance the reliability of this device. Also the intended use of these devices is very similar.

In summary and conclusion the VÄNNA Bathing System is "substantially equivalent" to the Century Bathing System, Sanitas Bathing System and the Smart Tub as to pre-market notification purposes. We respectfully request the FDA's concurrence with this conclusion.

This pre-market notification and its enclosures are being submitted in triplicate. Please do not hesitate to contact us if you have any questions or need additional information.

Sincerely,

A handwritten signature in black ink, appearing to read 'James A. Vanderheiden', is written over a faint, larger version of the same signature.

James A. Vanderheiden
President

JVA/gd
Enclosures



FEB 16 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. James A. Vanderheiden
President
VANCARE, Inc.
1515 1st Street
Aurora, Nebraska 68818

Re: K993872
Trade Name: VANNA Bathing System
Regulatory Class: II
Product Code: ILJ
Dated: January 28, 2000
Received: January 31, 2000

Dear Mr. Vanderheiden

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) 594-4595. 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 

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K993872

DEVICE NAME: VANNA Bathing System

INDICATIONS FOR USE:

The intended use of this device is the bathing and hygiene of residents/patients in hospitals, nursing homes, or assisted living facilities. The indications for use are the necessity and advisability of a clean and healthy environment in these facilities to prevent the spread of disease.

for 
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993872

(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)