



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 14 1994

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

Mr. Jeffrey Szmanda
Health Care Keyboard Company, Inc.
N82 W15340 Appleton Avenue
Menomonee Falls, Wisconsin 53051

Re: K930044
Comfort™ Keyboard System
Regulatory Class: II
Product Code: ILQ
Dated: December 28, 1992
Received: January 5, 1993

Dear Mr. Szmanda:

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 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.

Any claims which imply that the device may reduce pain, or ameliorate or prevent Carpal Tunnel Syndrome (CTS) would be considered a major modification in the indicated use of the device. This includes any references to CTS, the article entitled "An ergonomics guide to carpal tunnel syndrome", or the explanation of how tendons moving through a bent wrist can become irritated. The use of these claims would require a premarket notification submission (21 CFR 807.81).

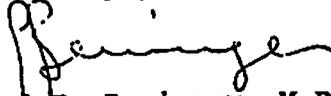
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In

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addition, the Food and Drug Administration (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 immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. 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), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-300) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



Paul R. Beninger, M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health



510(k) Summary

Health Care Keyboard Company, Inc.
N82 W15340 Appleton Avenue
Menomonee Falls, WI 53051

(414) 253-4131
Contact person: Jeffrey Szmanda

The Comfort™ Keyboard System is similar to a regular computer keyboard in all aspects except adjustability. The key arrangement is the same. The materials used and the physical properties of the materials used are the same as a regular keyboard. The electronic signals to the computer also are the same. Please see page 33 of the proposed User's Manual for technical information about the product. This product meets all standards set forth in ANSI/HFS 100/1988 (see enclosed copy) except for Keyboard Height and Slope, which is designed to be adjustable in order to improve typing postures among individual users.

The only difference, in fact, is that the Comfort™ Keyboard System is designed to be more comfortable by adjusting to the natural posture of individual users.

This keyboard is designed in three sections -- one with the keys assigned to the left hand, another with the keys assigned to the right hand, and the separate numeric keypad. Each section is mounted on its own universal telescoping mount, which allows the section to be separated, raised, lowered, rotated and tilted. This permits each section to be adjusted easily to reduce the awkward posture required by flat keyboards.

The awkward postures associated with flat keyboards include pronation (rotating the hands palms-down), ulnar deviation (bending the wrists inward) and extension (raising the fingertips).

The desired natural typing posture can be demonstrated easily: beginning with the hands hanging relaxed by the sides, bend the elbows to bring the forearms parallel to the floor while maintaining the same neutral hand-wrist-arm relationship. Please see enclosed "Ergonomics Guides" for the reference to this design principle.

Each section thus can be adjusted to each individual's natural typing posture. Because people come in all shapes and sizes, a keyboard must be totally adjustable, as this keyboard is, in order to adapt to a wide range of natural postures.

The numeric keypad can be relocated to the left for left-handed users, and the sections can be adjusted for use in the standing position.

Occupational therapists are pointing out that the keyboard will contribute to the effectiveness of rehabilitation programs because it is more comfortable and eliminates unnecessary strain on the wrists and arms.



(2)

The Johns Hopkins University has recognized a prototype of this keyboard with a National Finalist-Merit Award in the university's National Search for Computing Applications to Assist Persons with Disabilities. The basis for the award was that the sections can be adjusted to provide more comfortable access to people with physical limitations. Intended use for special needs is described on pages 18-22 of the draft copy of the proposed User's Manual. This section was prepared by the University of Wisconsin-Stout, Center for Rehabilitation Technology.

The balance of the User's Manual was prepared by Marilyn Dainoff, ergonomic consultant and coauthor of a book entitled, "People and Productivity - A Manager's Guide to Ergonomics in the Electronic Office. Marvin Dainoff, also coauthor, is the Director of the Center for Ergonomic Research at Miami University, Ohio.

The company will make no health claims relating to this product. All information and promotional materials will address the issues of comfort and posture only; no claims will be made that the product will diagnose, treat, prevent, cure or mitigate any condition. The strongest statement that we would make is that the keyboard will eliminate unnecessary strain on the wrists, arms and shoulders. Disclaimers are found on page 4 of the proposed User's Manual.

