DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 1998

Ms. Karen Gotfredson
President
NK Biotechnical Corporation
10850 Old County Road 15
Minneapolis, Minnesota 55441

Re: K981730
Trade Name: Digit-Grip with LCD, Model DGR 002
Regulatory Class: II
Product Code: LBB
Dated: May 12, 1998
Received: May 15, 1998

Dear Ms. Gotfredson:

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,

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 (if known): K981730

Device Name: Accessories for Digit-grip with LCD

Indications For Use: Model # 16K002

Karen Gayfield
President

INDICATIONS FOR USE: The ULTIMATE System is indicated for use as follows:

1. to measure grip or pinch strength in an injured and uninjured hand.
2. to follow an injury through the rehabilitation process and measure progress or lack of progress, in terms of grip or pinch strength, of the therapy regimen or medical treatment.
3. to document baseline grip or pinch strength of the hands and lifting, pulling and pushing strength capabilities of employees and to monitor the strength of employees in the work-place over time.
4. generally, in any situation where the hand grip or pinch strength would be a valuable piece of data in the evaluation of a person who has sustained an injury or suffers a disease to his/her hand(s).
5. to establish an industrial strength testing program in general, and to match the strength of workers to the strength demands of specific job duties in the workplace (lifting, pulling and pushing protocols) in a simulated test.
6. to conduct pre-employment screening for physically demanding job activities.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981730

Prescription Use___ OR Over-The-Counter Use X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)