Mr. Howell H. Michael
General Manager
Clinitex Medical Corporation
9801 Kincey Avenue, Suite 100
Huntersville, North Carolina 28078

DEC - 9 1997

Re: K973417
    Clinitex® Stockinette
    K973420
    Clinitex® Cast Padding
    Regulatory Class: I
    Product Code: LGF
    Dated: September 9, 1997
    Received: September 10, 1997

Dear Mr. Michael:

We have reviewed your Section 510(k) notification of intent to
market the devices referenced above and we have determined
these devices are substantially equivalent (for the
indications for use stated in the enclosures) 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 devices, 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 devices are classified (see above) into either class
II (Special Controls) or class III (Premarket Approval), they
may be subject to such additional controls. Existing major
regulations affecting your devices 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 devices in the Federal Register. Please note:
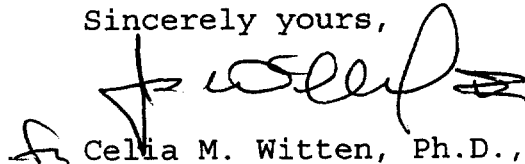this response to your premarket notification submission does

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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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

Enclosures

510(k) Number: <u>K973417</u>

Device Name: <u>Clinitex Stockinette</u>

Indications For Use: Clinitex® Stockinette is a tubular textile used to form the first protective layer (base) of an orthopedic cast below the cast padding and cast tape. The polyester material help repel water and dry rapidly.

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

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·· Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of General Restorative Devices
510(k) Number _____ K973417

Prescription Use ___   OR   Over-The-Counter Use _X_
(Per 21 CFR 801.109)   (Optional Format 1-2-96)