

SEP 23 1998

K982960



4445-310 S.W. 35th Terrace
Gainesville, Florida 32608
TEL: 352/338-0440 FAX: 352/338-0662

510(k) SUMMARY

APPLICANT: Medical Device Technologies, Inc.
4445-310 SW 35th Terrace
Gainesville, FL 32608

CONTACT: Karl Swartz
Quality Assurance Manager

TELEPHONE: (352)338-0440
fax (352)338-0662

TRADE NAMES:Medical Device Technologies, Inc. Tru-Core™ Disposable Automatic Biopsy Instrument

COMMON NAME: Disposable handle gun for use with disposable biopsy needles.

CLASSIFICATION NAME: Instrument, Biopsy, No. 78KNW

SUBSTANTIAL EQUIVALENCE:

<u>Company Name</u>	<u>Product Name</u>	<u>510(k) No.</u>
Medical Device Technologies	Tru-Core	K962969
Medical Device Technologies	Tru-Core Semi-Automatic	K982085

DESCRIPTION OF DEVICE:

The Tru-Core™ Disposable Automatic Biopsy Instrument is intended for use in obtaining multiple core samples from soft tissue such as the liver, kidney, prostate, breast, and various soft tissue lesions. It is not intended for bone.





SEP 23 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Mr. Karl Swartz
Quality Manager
Medical Device Technologies, Inc.
4445-310 S.W. 35th Terrace
Gainesville, FL 32608Re: K982960
Tru-Core™ Disposable Automatic Biopsy Instrument
Dated: August 20, 1998
Received: August 24, 1998
Regulatory Class: II
21 CFR 876.1075/Procode: 78 KNW

Dear Mr. Swartz:

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 requirements, 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) 594-4613. 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/dsma/dsmamain.html>".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



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TEL: 352/338-0440 FAX: 352/338-0662

510(k) Number (if known): K982960

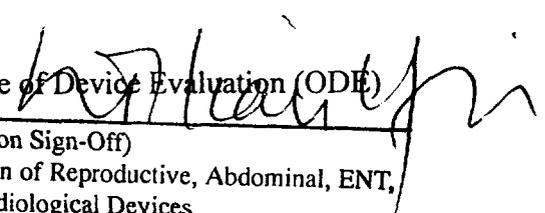
Device Name: MD Tech Tru-Core™ Disposable Automatic Biopsy Instrument

Indications for Use:

The Tru-Core™ Disposable Automatic Biopsy Instrument is intended for use in obtaining multiple core samples from soft tissue such as the liver, kidney, prostate, breast, and various soft tissue lesions. It is not intended for bone.

(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 Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K982960

Prescription Use
(Per 21 CFR 801.109)

OR Over-The-Counter Use

(Optional Format 1-2-96)

