



3600 SW 47th Avenue  
Gainesville, Florida 32608  
TEL: 352/338-0440 FAX: 352/338-0662

### 510(k) SUMMARY

**APPLICANT:** Medical Device Technologies, Inc.  
3600 SW 47<sup>th</sup> Avenue  
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™ I  
Reusable Biopsy Instrument

**COMMON NAME:** Reusable 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 Reusable	K962969
Medical Device Technologies	Tru-Core Automatic Disposable	K982960

#### DESCRIPTION OF DEVICE:

Our company is presently authorized by the Food and Drug Administration to manufacture a reusable handle gun K962969 that utilizes the same disposable soft tissue biopsy needles as the disposable version of this gun, K982960. This new device has the same operation and firing cycle as the disposable gun, but is intended to be reusable, as in the gun submitted under K962969. This new device will also utilize the same disposable soft tissue biopsy needles.

The biopsy needle is guided into position utilizing external guidance (Ultrasound, Mammography, etc.). The device consists of a spring powered, reusable handle, and a disposable needle set. To operate, the needle set is loaded into the reusable handle, the device is "cocked", then "fired" into the appropriate site, and tissue (specimen) is retrieved from the needle set for laboratory evaluation and diagnosis. Specifically, when "fired", the inner part of the needle set (stylet) moves forward first, penetrating the biopsy site. Tissue fills a "slot" at the tip of the stylet.





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### 510(k) SUMMARY(Cont.)

Then the outer part of the needle set (cutting cannula) advances forward slicing off the tissue in the slot and enclosing it during removal from the patient. The tissue specimen is removed from the stylet slot after placing the device in the sample retrieval position. The procedure is repeated for additional biopsies, if dictated by the physician

#### Indications for Use:

The Tru-Core™ I Reusable 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.





MAY 20 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Mr. Karl Swartz  
Quality Manager  
Medical Device Technologies, Inc.  
3600 SW 47<sup>th</sup> Avenue  
Gainesville, Florida 32608Re: K990839  
MD Tech Tru-Core™ I Reusable Biopsy Instrument  
Dated: March 5, 1999  
Received: March 15, 1999  
Regulatory Class: II  
21 CFR §876.1075/Product Code: 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 legally marketed predicate 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,

CAPT Daniel G. Schultz, M.D.  
Acting 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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510(k) Number (if known): K99

Device Name: MD Tech Tru-Core™ I Reusable Biopsy Instrument

Indications for Use:

The Tru-Core™ I Reusable 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)

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

*David A. Seymour*  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K990839

