

K961959

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## 510(k) SUMMARY

**APPLICANT:** Medical Device Technologies, Inc.  
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Gainesville, FL 32608

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**TRADE NAMES:** Medical Device Technologies, Inc. and/or MD  
TECH Biopsy Set For Bone and Bone Marrow

**COMMON NAME:** Bone and/or bone marrow aspiration/biopsy  
needles.

**CLASSIFICATION NAME:** Needle, Biopsy, Cardiovascular,  
No. 79DWO

### SUBSTANTIAL EQUIVALENCE:

<u>Company Name</u>	<u>Product Name</u>	<u>510(k) No.</u>
Mannan Medical Products	Bone Marrow Biopsy Needle	K890925
Mannan Medical Products	Super Core Biopsy Needle	K930732
Mannan Medical Products	Bone Marrow Harvest Needle	K940025
Sherwood Medical	Monoject Bone Marrow Needle	K945109

### DESCRIPTION OF DEVICE:

Our company is presently authorized by the Food and Drug Administration to manufacture soft tissue biopsy needles, K944837 The bone biopsy needle is a variation of this needle.

The MD Tech Biopsy-Set is intended for the purpose of harvesting bone and/or bone marrow specimens.

The MD Tech Biopsy-Set Bone and Bone marrow is inserted percutaneously, adjacent to the biopsy site. Access to the bone and/or bone marrow specimen(s) is achieved mechanically via cutting surfaces on the device. Harvesting of bone and/or bone marrow specimen(s) is accomplished both by mechanical and negative pressure (aspiration), which is created by attaching a syringe to a fitting on the outer cannula of the device. Specimen(s) are contained within the outer cannula during withdrawal from the patient.