510(k) SUMMARY of Safety and Effectiveness
(Pursuant to 21 CFR 807.92)

I. GENERAL

A. Submitted By: TZ Medical Inc.
7272 S.W. Durham Road #800
Portland, Oregon 97724

B. Contact Person
Madalyn C. Duncan
Regulatory Specialist

C. Proprietary Name:
PadTac Electrophysiology Recording Catheters
PadTac Junction Cable Connector
PadTac Cable

D. Classification Name: Electrode Recording Catheter

E. Classification: Class II, Cardiovascular DRF,
CFR 870.1220

II. DEVICE INFORMATION SUMMARY

A. Predicate Device
IBI 1100 Electrophysiology Catheter System
K961924
IBI 1000 Electrophysiology Catheter System
K946333

C. Device Description
The PadTac Electrophysiology catheters are
between 5 and 8 french (fr), 4, 10, 12 and 14 pole,
fixed, monitoring and recording.

The multi-electrode electrophysiology catheters are
used for electrophysiology electrocardiograph
recording and cardiac stimulation during diagnostic
procedures. The cables and box serve as an
extension between the catheter and the pin block.

B. Device Intended Use

The fixed PadTac electrophysiology mapping and recording catheters and PadTac cables are
used for recording intracardiac electrogram (EGM) and for cardiac stimulation during
diagnostic electrophysiology studies. The catheters will be used in the high right atrium, right
ventricular apex and HIS bundle (recording only). The cables and box connect the catheter
to the recording system.

PadTac Electrophysiology Catheter and Cables
III. SUBSTANTIAL EQUIVALENCE TESTING SUMMARY

The TZ Medical PadTac EP Catheters have been tested and are considered safe and effective per "Electrode Recording Catheter Preliminary Guidance", Mark Massi, Pacing and Electrophysiology Device Branch, Division of Cardiovascular, Respiratory and Neurological Devices, Office of Device Evaluation FDA, CDRH, 1995.

The TZ medical PadTac cables have been tested and are considered safe and effective per "Standard for Medical Equipment; Part 1: General Requirements, UL 2601 (IEC 60601-1)."
Dear Ms. Duncan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA’s issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act’s requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Device Name: PadTac Mapping and Recording EP Catheters:

Indications for Use:

The fixed PadTac electrophysiology mapping and recording catheters and PadTac cables are used for recording intracardiac electrogram (EGM) and for cardiac stimulation during diagnostic electrophysiology studies. The catheters will be used in the high right atrium, right ventricular apex and HIS bundle (recording only). The cables and box connect the catheter to the recording system.