FHC Microneurography Electrodes (referred to as needles by many) were developed to record multi-unit peripheral nerve activity. They have been refined over the years by working in conjunction with the investigators who use them. The tip taper is dramatically shorter and broader than our standard microelectrodes and convex to facilitate a minimally painful penetration through the skin. Our Microneurography Electrodes are available in an uninsulated configuration as well for use as a reference electrode.

FHC intends to clear these devices via 510(k). The FDA product code applicable to this product is, GXZ

Part 882, Neurological Devices, Subpart B - Neurological Diagnostic Devices

Sec. 882.1350 Needle electrode.

(a) *Identification.* A needle electrode is a device which is placed subcutaneously to stimulate or to record electrical signals.

(b) *Classification.* Class II (performance standards).

Indications For Use: Microneurography Electrodes are intended to be placed subcutaneously to stimulate or record electrical Nerve Potential signals. These electrodes are for single patient use only.

Currently, these devices are considered Investigational devices. Limited by Federal (or United States) law to investigational use and requires IRB Approval in accordance with Part 812, Section 812.2.

FHC, Inc. has reviewed and approve of the use of our Microneurography Electrodes in the following IRBs/ project numbers: