

K954737

JUL - 3 1988

**JTECH DYNATRACK
SURFACE ELECTROMYOGRAPH SYSTEM
PREMARKET NOTIFICATION 510(K)**

12. Summary of Safety and Effectiveness Data

12.1 Identification of Legally Marketed Device

The JTech Dynatrack SEMG System is substantially equivalent to the class II Targus Concepts Biostar SEMG System Device (K912938), the Tracker Microprocessor, and the Tracker PC Software of the Large Muscle Strength Gauge (K944630).

12.2 JTech Dynatrack SEMG System Description

The JTech Diagnostic Electromyograph is a device used by professional healthcare examiners to measure the bioelectrical signal produced by peripheral muscles. The main display of data (See Exhibit 1, page 20) is a simple chart recorder display which shows the clinician and patient the level of muscle tension in the body. Thus, neuromuscular activity may be monitored.

The data displayed on the monitor includes muscle activity in microvolts, the median frequency curve or power spectral curve. Display 3a of exhibit 3, shows the actual level of muscle tension in microvolts; display 3b shows the median bioelectric signal generated by the muscle over time; display 3c shows the bioelectric frequencies generated by the muscles at a moment in time.

Although the modalities of the three results appear to be the same, they provide different information to the healthcare professional.

12.3 Intended Use

The JTech Dynatrack Surface Electromyograph is a biofeedback device that provides a visual signal corresponding to the status of a patient's muscle activity. Healthcare professionals can use the machine to monitor the patient's muscle activity. This is a precise biofeedback instrument for quick and accurate assessment and recording of the bioelectric muscle signal. It is compliant with the National Bureau of Standards calibration standards for microvolts.

**JTECH DYNATRACK
SURFACE ELECTROMYOGRAPH SYSTEM
PREMARKET NOTIFICATION 510(K)**

12.4 Summary of Technological and Performance Characteristics of the JTech SEMG System as compared to the Biostar SEMG System and Large Muscle Strength Gauge

12.4.1 Dynatrack SEMG Microprocessor

The Dynatrack SEMG microprocessor is comprised of electronic hardware in a 5.5"W x 7.2"L x 1.75"H aluminum box. Standard patient electrodes with protected male and female connectors are attached to the Dynatrack microprocessor. These receive the muscle signal from the patient and convert it to a digital signal. The Dynatrack SEMG microprocessor may be used in two ways: It may be connected by cable directly to the PC's RS232 Serial Port, and the screen will display muscle activity. Or it may be connected through the JTech Tracker microprocessor, and readout multiple patient measurements on the PC screen. The latter configuration connects the Tracker microprocessor directly to the PC RS232 Serial Port. The firmware of the Tracker microprocessor first processes the muscle signal of the Dynatrack SEMG microprocessor, followed by signals from measurement peripherals linked to other electrode ports.

JTech Dynatrack SEMG electrodes and lead wires coming in contact with the patient are equipped with male jack connectors which can receive only shrouded female lead electrodes, in accordance with the FDA Public Health Advisory, December 28, 1993. This prevents the examiner from inadvertently plugging the electrodes into a power outlet.

The JTech Dynatrack SEMG microprocessor may be used in series with the JTech Tracker microprocessor. The Tracker has 12 channels to the PC, enabling comparison of Dynatrack muscle activity results with other patient conditions such as muscle strength. This is an improvement over the Biostar system, which has the limited capability of recording only the EMG muscle activity signal through the microprocessor and PC software.

**JTECH DYNATRACK
SURFACE ELECTROMYOGRAPH SYSTEM
PREMARKET NOTIFICATION 510(K)**

12.4.2 SEMG Software Module of the Tracker System

The JTech Dynatrack SEMG System uses the Tracker software of the JTech Large Muscle Strength Gauge to drive the SEMG software module. The SEMG module provides the same records, trends, and files as the Large Muscle Strength Gauge with one exception: the information is electromyograph muscle activity rather than muscle strength data. In all other ways, the SEMG software is equivalent to Tracker software of the Large Muscle Strength Gauge.

12.5 Conclusion

The requirements of JTech's Dynatrack SEMG System are the same as the basic functionality of the predicate device, as well as conventional SEMG systems that acquire and display SEMG data on computer monitors.

12.6 Statement of Truthfulness and Accuracy

JTech certifies to the best of our knowledge that all the data and information submitted in the JTech SEMG Premarket Notification are truthful and accurate and that no material facts have been omitted.