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Summary Of Safety And Effectiveness for the Accelerated Transmission Protocol (ATP™)

The accelerated transmission protocol may be used by transtelephonic ECG transmitters. This protocol allows the stored ECG data to be sent more rapidly over the communications link to the receiver. Three devices that incorporate the Advanced Transmission Protocol (ATP) are presented in this summary statement. They are the King Of Hearts, Express ATP, the King Of Hearts, Prince ATP, and the HeartCard ATP.

These devices are intended for use by patients who need to record their ECG during daily activities for subsequent transmission to a clinic, service, or hospital. These patients may have been instructed by their physician to record their ECG for the purpose of documenting transient symptoms which may suggest cardiac arrhythmia. The telephonic use of these devices allows the patient to receive advice based on their ECG and symptoms in a timely manner.

These devices are non-invasive, external ambulatory electrocardiographic (ECG) memory monitors. They are designed for evaluation of transient symptoms like dizziness, palpitations, and chest discomfort, and may be incorporated as part of rehabilitation, or medical treatment follow-up, where such symptoms may be present.

Features and functions are identical to the identified predicate devices with the addition of the ATP feature. The Accelerated Transmission Protocol feature does not play any part in the recording of ECGs. It is only active in the transmit mode. The ATP feature accelerates the transmission rate to 3 times the rate the data was acquired. The transmitters convert the data to an FM signal, which is sent to a receiver (LRC 2000 Receiver) designed to receive the ATP protocol. The receiver demodulates the FM signal back to the analog ECG waveform, and expands the received signal to the original scale by using an increased sampling rate (3x) and operating the chart drive at a 3x rate. The result is a chart strip showing the time scale of the original signal acquisition. The edge print on the ECG strip indicates that an accelerated transmission has been received from an Instromedix transmitter.

The safety and effectiveness of these devices using ATP is substantially equivalent to the predicate devices. There are no known contraindications for use of this type of device. In our opinion, the ATP in these device provides a non-significant risk to the host, which are Class II, non-significant risk devices.