K961975

9.0 SUMMARY OF SAFETY AND EFFECTIVENESS JAN 30 1997

"510(k) SUMMARY"

9.1 Trade/Proprietary Name: Disetronic D-MODEM

9.2 Common/Usual Name: Telephonic Communication Modem

9.3 Classification Name: Infusion Pump - Accessory

9.4 Comparison to Currently Marketed Devices

The modified D-MODEM is substantially equivalent to the currently marketed D-MODEM (K943952). The design, materials and construction of the modified D-MODEM are identical to the currently marketed D-MODEM with the exception of the additional serial communications port capability. The use of an infra red serial communications port as an alternative to a direct serial communications port does not raise any significant new questions of safety or effectiveness.

9.5 Device Description

9.5.1 Discussion

The D-MODEM has been modified by adding an alternative serial communication outlet that uses Infra red light as the means of communication. The current serial port requires a direct electrical connection to allow the signals to be transmitted. The infra red port sends and receives light impulses that are converted to the same electrical signals before transmission over the telephone lines.

This modification was implemented to take advantage of the ability of the infra red port to achieve communication without any direct electrical connections. The absence of a direct electrical connection eliminates the potential for leakage or transmission of unwanted electrical current.. This allows the user, via a modem connected through a telephone line, to electronically link the pump to the computer in a doctor's office for communication purposes without having to interrupt his therapy.

9.5.2 Physical Specifications

9.5.2.1 'Modified' components

The original D-Modem (K943952) was designed and manufactured with the all of the circuits and components necessary for the IR interface. These were not discussed in the original submission as they were not capable of functioning with any device available in the U.S. at that time. The IR components and circuits specific to the use of the IR interface are detailed in Appendix II, A and B.

In principal, this infrared (IR) interface works the same way as any IR interface that allows a personal computer to be "connected" to an accessory such as a printer. Although the operation is similar in principal to a computer and printer connected via an IR interface, the big difference is the distance involved. The D-MODEM and the Pump have a very small infrared light range and must be placed in very close proximity to each other (see Instructions for Use). The positioning pin on the D-MODEM, which mates to the Pump in only one way, ensures proper positioning.

The transmission between the D-MODEM and the Pump utilizes amplitude modulation while other IR devices, such as TV remotes, utilize pulse modulation. In addition to the necessary distance, the D-MODEM and Pump transmission accuracy is verified by the communication protocol via a CRC-16 checksum (See Appendix II, D).

The original D-Modem was designed and manufactured with the all of the circuits and components necessary for the IR interface. These were not discussed in the original submission as they were not capable of functioning with any device available in the U.S. at that time. The IR components and circuits specific to the use of the IR interface are detailed in Appendix II, A and B.

A schematic diagram of the IR circuitry is also attached as Appendix II, B.

9.5.2.2 Operational Specifications

9.5.2.2.1 Serial Port Communication

The modified device is capable of infra red communication as well as direct connection to the serial port. In principal, this infrared interface works the same way as the IR interface that allows a personal computer to be "connected" to an accessory such as a printer. Although the operation is similar in principal to a computer and printer connected via an IR interface, the big difference is the distance involved. The D-MODEM and the Pump have a very small infrared light range and must be placed in close proximity to each other (see Instructions for Use). The positioning pin on the D-MODEM, which mates to the Pump in only one way, ensures proper positioning.

The transmission between the D-MODEM and the Pump utilizes amplitude modulation while other IR devices, such as TV remote control devices, utilize pulse modulation. In addition to the necessary distance, the D-MODEM and Pump transmission accuracy is verified by the communication protocol via a CRC-16 checksum (See Appendix II, D).

9.5.2.2.2 Environmental Susceptibility

The modifications do not have any effect on the susceptibility of the unit to withstand environmental influences. The ability of the unit to perform within specifications under normal temperature and pressure variations and its ability to withstand electrostatic discharge (ESD) and Electromagnetic interference (EMI) has not changed. As stated above, the difference in the type of IR modulation, as well as the very small

range of the IR sensor shields the device from interference by other IR sources. Additionally, the safety systems in the pump described in the pump submission, preclude other IR sources from interfering with pump operation.

9.5.3 Intended Use

The D-MODEM is Intended to facilitate telephonic communication between a Personal Computer (PC) and the Disetronic Infusion Pumps. The modified device adds the Disetronic Multifuse Infusion Pump to the list of compatible pumps.

9.6 Conclusion

Disetronic Medical Systems has concluded that the minor modification to the D-MODEM has not significantly changed the safety or effectiveness of the device. The modified D-MODEM, with the addition of the Disetronic Multifuse Infusion Pump as a compatible pump for which the device is intended to be used, is substantially equivalent to the currently marketed device.