

## Operational Description

The InPen™ is a reusable pen injector (Product Code FMF, 21 CFR 880.5860) designed for single patient use by diabetics for the self-injection of insulin. The pen injector is compatible with FDA-approved 3 ml (U-100) insulin cartridges and single-use detachable and disposable pen needles. The pen injector allows the user to dial the desired dose from 0.5 to 30 units in one-half (1/2) unit increments.

The intended dose is mechanically set by the user by rotating a dose knob. The insulin is injected by manually depressing the dose knob which causes the piston in the insulin cartridge to expel the intended dose. The device contains a non-replaceable battery and electronics to communicate via Bluetooth® with an accessory application (“app”) on an Android™ or iOS® mobile device.

The mechanical device design is nearly identical to that of existing pen injectors with the exception that the device uses a relative encoder to convert the plunger motion into a digital signal. The signal is processed and communicated to the App to display the delivered dose. There is no way to deliver a dose via the wireless link - the dose must be expelled by physically depressing the plunger.

The electronics assembly consists of a two-layer flexible PCB containing the CC2541 (Texas Instruments) system-on-a-chip, balun and antenna, encoder pads, and supporting electronics.