

FCC ID marking for the transmitter in PressureWire® Aeris. (Rev 02)

Background:

PressureWire® Aeris is a guidewire for pressure measurement of intravascular pressure in the heart and, coronary and peripheral blood vessels.

The transmitter which is part of the PressureWire® Aeris is outside the body.

PressureWire® Aeris including transmitter is sterile and for single use only.

The transmitter transfers measured pressure signal in the 2.4 GHz frequency band to the PressureWire® Receiver, which is connected to a cathlab hemodynamic recording system.

About normal size of the transmitter:



Marking:

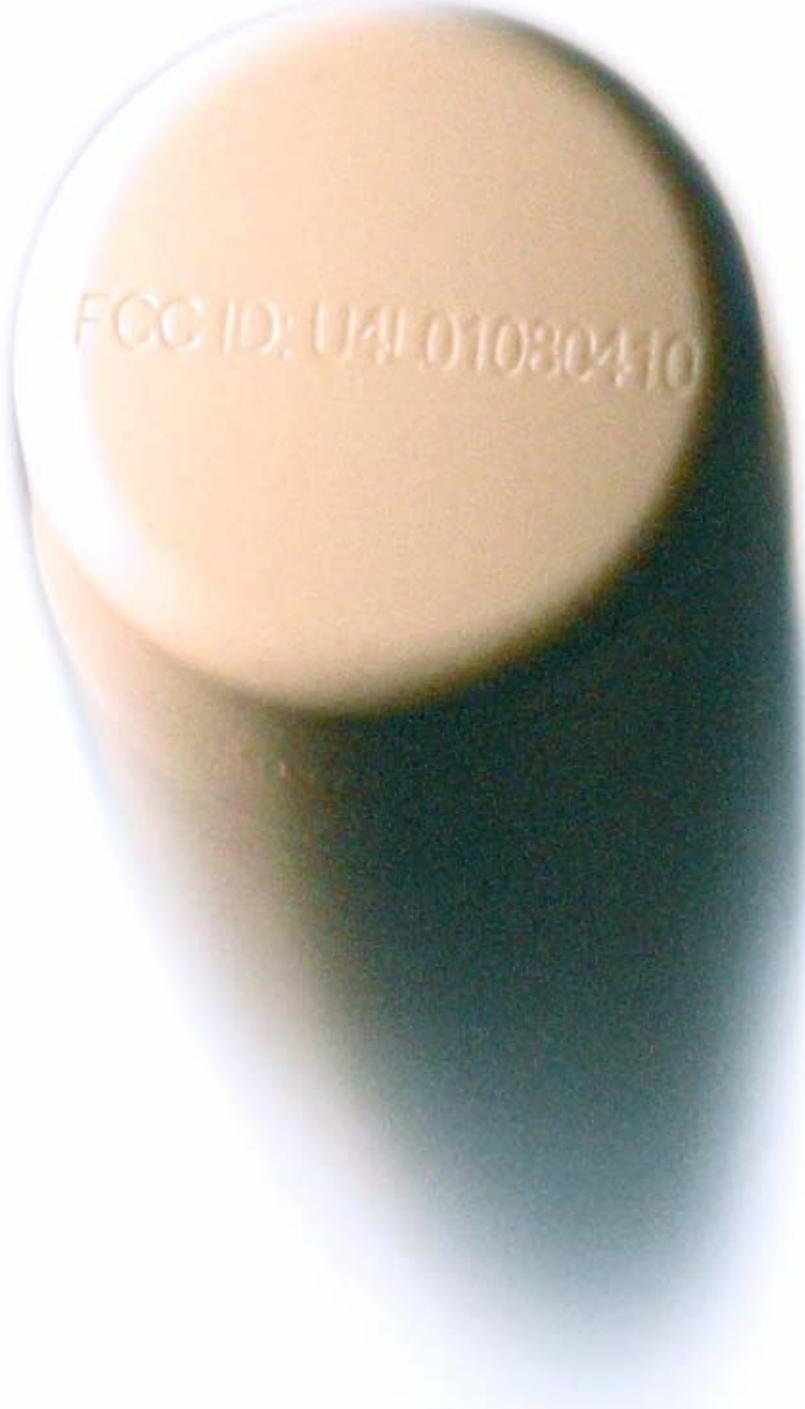
PressureWire® Aeris is delivered in a Tyvek pouch which is marked with a label including the FCC ID, see Attachment I, Label PressureWire® Aeris.

The FCC ID: U4L01080410 is visible at the housing end of the transmitter. The text is very small but visible see next page for an enlarged picture.

Moreover the FCC ID is mentioned in the Instructions for Use (IFU) for the product.

Normal handling:

PressureWire® Aeris is unpacked from the packaging- a Tyvek pouch, used during the examination and treatment of the patient for a couple of hours and then disposed. The PressureWire® Aeris including transmitter is contaminated after use.



FCC ID: U4101030410