Eric Jameson - RE: quick question on Corona

From: "Reed, Craig" <CReed@novoste.com>
To: "Eric Jameson" <EJameson@mail.dnr.state.ga.us>
Date: 03/21/2002 15:14
Subject: RE: quick question on Corona

The shorter trains/devices are not being considered in the FDA trials for the Corona System.

The transfer device approved by the FDA for use in the MOBILE trial in the Corona System is the A1730. We are not planning to give the Corona System Transfer Device (A1730) a model number different that the Beta-Cath System Transfer Device (A1730) because they have the same features. If we change the auto-off timing value for the A1730, all A1730 devices will be upgraded to the same time-out value. The A1760 model number will only be used if we decide that it is not practicable to upgrade all A1730 devices to a new time-out value. For clarification, you may state that the Model A1760 requires review by the FDA prior to use in clinical trials or distribution. In any case the auto-off time-out value for each device is communicated in it's respective User's Manual.

I'm still reviewing the certificate.

Thanks,

Craig
-----Original Message-----
From: Eric Jameson [mailto:EJameson@mail.dnr.state.ga.us]
Sent: Thursday, March 21, 2002 10:41 AM
To: Reed, Craig
Subject: quick question on Corona

Craig,

I wanted to get some clarification on the Corona system. Referring back to your e-mail on 10/11/2001 and letter dated 11/5/2001, it states that the Corona will utilize the A1730 transfer device (60 mm BEBIG source train) and the 4 lumen (7 Fr) catheter.

Are the shorter source trains (found in A1732 and 1733) being considered in the FDA trials for use as Corona systems?

Also, the Corona device is identified as the A1760 device in the e-mail. I know I originally mentioned just calling it the A1730, but after discussion w/Rod, it probably would be a good idea to give the Corona system its own model number, thus going back to the A1760.

Talk to you soon,

Eric Jameson