

PREMARKET NOTIFICATION

VII: 510(K) SUMMARY

K953676

Manufacturer: NAMIC U.S.A. Corporation
Glens Falls, New York 12801

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Contact Person: Mary Meagher Rubin
Regulatory Affairs Specialist

Telephone Number (518) 798-0067
Facsimile Number (518) 798-5475

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Trade Name: Breeze™ Digital Balloon Inflation Device

Common Name: Balloon Inflation Syringe

Classification Name: Syringe, Balloon Inflation

The Breeze Digital Inflation Device, like its predicates, the Morse Balloon Inflation Device and the Merit Monarch Inflation Syringe is a Balloon Inflation Syringe. These devices are intended for balloon inflation/deflation and to measure the pressure within the balloon during angioplasty procedures.

A Balloon angioplasty catheter provides a fluid column which communicates pressure inside the balloon to the digital pressure gage. The gel acts as a vibratory membrane, allowing the signal to be passed to the sensor. The analog signal from the sensor is then displayed on the liquid crystal display of the gage. The manual timer operates independently of the above mentioned pressure gage. The timer is started and stopped by depressing the Start/Stop button and can be reset to 00^m00^s by depressing the Reset Button.

The Breeze Digital Inflation Device shares a common design with the Morse Balloon Inflation Device in that they both are comprised of a clear syringe barrel with an attached pressure gauge, a threaded plunger and a latching mechanism that operate in tandem to generate and control balloon inflation pressure. The Breeze Digital Inflation Device has in common with the Merit Monarch Inflation Syringe, a digital pressure gauge.

VII. 510(K) Summary (Continued).

Biocompatibility testing has been performed on the Morse Balloon Inflation Device (K904275), the Transducer Manifold (K902472), the Contrast Controller (K903493), and the Hemostatic Introducer Sheath (K915078). These devices have all been previously cleared through Premarket Notification.

The material composition of the fluid path of the Breeze Digital Balloon Inflation Device is identical to the currently marketed NAMIC products, named above.

The Breeze Digital Inflation Device differs from the Morse Balloon Inflation Device with regard to design in the following ways: 1) the latching mechanism is actuated differently; 2) a digital pressure gauge replaces an analog Bourdon tube pressure gauge; 3) the elastomeric closure for the new device is an O-ring vs. a stopper; 4) the gauge pressure rating has been increased from 22 ATM to 30 ATM; and 5) the total syringe volume is increased from 12 to 25 cc's.

The digital gauge used for the Breeze Digital Inflation Device differs from the one used in the Merit Monarch Inflation Syringe in that the latter contains a software driven microprocessor whereas the proposed NAMIC gauge utilizes non software driven solid-state circuitry.

The Breeze Digital Inflation Device has been subjected to non-clinical performance testing to provide data supporting the gauge pressure rating and accuracy claimed on the label. (ie: 0-30 ATM \pm 2% of full scale). The results of the tests do support the claimed pressure and accuracy.