MAY 30 1996

K960983

Summary of Safety and Effectiveness

I. General Information

Device Generic Name: Inflation Device

Device Trade Name: Medtronic® Everest™ 30 Inflation Device / Survival Kit

Applicant's Name and Address:

Medtronic Interventional Vascular, Inc.
37A Cherry Hill Drive
Danvers, Massachusetts 01923

II. Description of the Diseases and Conditions for Which the Devices are Indicated

The Indications for the Medtronic® Everest™ 30 Inflation Device / Survival Kit are identical to those for commercially available inflation devices. The devices are used for the inflation / deflation of balloon dilatation catheters. These devices are intended for single use.

III. Device Description

The Medtronic® Everest™ 30 Inflation Device is a sterilized, single use device intended as an accessory to balloon dilatation catheters. The Everest™ 30 Inflation Device will be used to inflate and deflate balloon dilatation catheters during angioplasty procedures. The device contains an analog pressure gauge which will read the inflation pressure of the balloon catheter. The pressure gauge is isolated from the syringe fluid with use of a bouron tube and is graduated in 0.5 atmosphere / bar increments to a 30 atmosphere / bar maximum. The device has a twenty (20) cubic centimeter syringe to hold a contrast medium for balloon inflation. The device has a plunger engaging mechanism. When engaged, the plunger, which applies contrast medium to the syringe, is rotated in a clockwise direction by the user to slowly increase the syringe pressure or in a counter - clockwise direction to slowly decrease the syringe pressure. When disengaged, the plunger can be manually retracted to rapidly apply vacuum and advanced to rapidly apply syringe pressure. The inflation device is connected to the balloon catheter manifold via a high pressure connecting tube which terminates into a male luer fitting. The inflation device also contains an accessory three way stopcock for preparation procedures.

The inflation device may also be provided as a Survival Kit. The Survival Kit includes one (1) Y-Adapter with Hemostasis Valve, one (1) Guide Wire Introducer and one (1) Guide Wire Torque Handle.

IV. Alternatives

Alternatives for patients requiring interventional procedures includes medical therapy and surgery. Alternatives to use of the Medtronic® Everest™ 30 Inflation Device / Survival Kit are other commercially available inflation devices.

V. Potential Adverse Effects

Potential adverse effects of interventional procedures include: vessel trauma at the treatment site, vessel occlusion, localized dissection, vessel spasm or thrombosis. Total occlusion in the absence of collateral blood supply in coronary arteries could cause severe myocardial ischemia, and if not properly relieved, acute myocardial infarction and death may ensue. Other adverse effects are potentials for routine catheterizations. These include hypotension, bradycardia, reaction to contrast media, air emboli, nausea, palpitations, angina, minor atrial or ventricular rhythm disturbances and general discomfort. Local complications at the site of catheter introduction include vascular thrombosis, hematoma, other bleeding complications, infection and pain or tenderness. The Medtronic® Everest™ 30 Inflation Device / Survival Kit are used as accessories for these procedures.

VI. Summary of Studies

Testing of the devices for safety and effectiveness included the following:

Pressure Gauge Accuracy Test, Leak Test and Pressure Test.

Pressure Gauge Accuracy Test:

Inflation devices were tested for their gauge accuracy. All samples were previously EtO sterilized. Each device was filled with water and connected to a calibrated pressure gauge. Each device was pressurized to three (3) settings, 4 ATM (59 psi), 16 ATM (235 psi) and 27 ATM (397 psi). Once the desired pressure was achieved, the device's gauge was compared to the calibrated gauge reading. This testing showed results comparable to other commercially available inflation devices.

Leak Test:

Each device was pressurized with water at 200 psi, 350 psi and 500 psi. Each device was filled with water, then all air bubbles were removed. Each device was then connected to a calibrated high pressure gauge, and pressurized to the indicated pressures. Each pressure setting was held for two (2) minutes, and the device was observed for any water leakage. This testing showed results comparable to other commercially available inflation devices.

Pressure Test:

Each device was filled with 10 cc of water and connected to a calibrated high pressure gauge. Each device was inflated until the calibrated high pressure gauge read 600 psi. This testing showed results comparable to other commercially available inflation devices.

Biocompatibility of Materials / Finished Devices:

Biocompatibility testing was not required due to material changes not being involved with the fluid path of the device. Refer to K942269 for biocompatibility testing for the Medtronic® Everest™ Inflation Device.

VII. Conclusion

The testing performed for the Medtronic® Everest™ 30 Inflation Device / Survival Kit provides reasonable assurance that the device will perform in a safe and effective manner when used as indicated.

I believe, to the best of my knowledge, that all data and information submitted in the 510(k) are truthful and accurate, and that no material fact has been omitted.

Joseph O. Magliozzi

Joseph O. Magliozzi RAC
Sr. Regulatory Affairs Specialist