K960055 SEP 30 1996

PREMARKET APPROVAL NOTIFICATION CERTIFICATION AND SUMMARY

(To be submitted when claiming equivalence to a Class III device)

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

I certify that I have conducted a reasonable search of all information known or otherwise available to me about the types and causes of safety and/or effectiveness problems that have been reported for the BioGlide Vascular Catheter, single lumen. I further certify that I am aware of the types of problems to which the BioGlide Vascular Catheter, single lumen is susceptible and that the following summary of the types and causes of safety and/or effectiveness problems about the BioGlide Vascular Catheter, single lumen is complete and accurate.

Complications associated with the use of the device may be similar to those experienced in any other surgical procedure carried out under local and/or general anesthetic:

Reactions to drugs or anesthetic agents;
Electrolyte imbalance;
Excessive Blood loss;

Local and Systemic Infections are not uncommon with this type of procedure. They are most usually due to organisms that inhabit the skin, particularly *Staphylococcus epidermidis*. However, other pathogens circulating in the blood stream may colonize the device and in the majority of patients require its removal.

Other potential complications are listed:

Catheter or cuff erosion through skin
Catheter malposition, occlusion, fibrin sheath formation at tip, dislodgment, or rupture
Intolerance reaction to implanted device
Vascular thrombosis
Perforation or laceration of vessels or viscous
Pneumothorax, hemothorax, or hydrothorax
Postural related catheter occlusion, damage, or breakage due to catheter crimping between the clavicle and first rib
Endocarditis
Cardiac arrhythmia
Thrombophlebitis
Sepsis or infection
Embolus
Brachial plexus injury
Hematoma
Cardiac tamponade
Exit site necrosis

A Bibliography or other citation of the materials upon which the above summary is based is found in Attachment 7 of this submission.

Printed name of person required to submit 510(k): Tom Holdych

Signature of person required to submit 510(k): 

Title of person submitting 510(k): Director Regulatory Affairs and Quality Assurance

Name of Company: Medtronic PS Medical Corporation

Date: 1/3/96