510k) Summary

Pursuant to 512(i)(3)(A) of the Food, Drug and Cosmetic Act, TeleMed Systems, Inc. is required to submit with this Premarket Notification either an "...adequate summary of any information respecting safety and effectiveness or state that information will be made available upon request of any person." TeleMed Systems chooses to submit a summary of the safety and effectiveness information. The summary is as follows:

Trade Name:	PPD™ Balloon Dilatation Catheter
Owner/Operator:	TeleMed Systems, Inc. 8 Kane Industrial Drive Hudson, MA 01749
Manufacturing Site:	TeleMed Systems, Inc. 8 Kane Industrial Drive Hudson, MA 01749
Device Generic Name:	Balloon Dilatation Catheter
Classification:	According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II, Performance Standards (78KNQ).
Predicate Devices:	GI balloon dilatation catheters marketed by TeleMed Systems and Boston Scientific

Product Description:
The PPD Balloon Dilatation Catheter consists of a polymer balloon mounted on a plastic shaft. The balloon can be inflated to different diameters depending on the inflation pressure; each balloon is capable of inflation to three or four distinct and progressively larger sized diameters at the recommended pressures. Proximal luer connectors are provided for balloon inflation and guidewire passage.

Indications for Use:
The TeleMed Systems PPD™ Balloon Dilatation Catheter is indicated for use in dilatation of gastrointestinal strictures of various etiologies (inflammatory, neoplastic, congenital, anastomotic) involving the esophagus, pylorus, biliary tract, sphincter of Oddi and colon.

Safety and Performance:
This submission is a Special 510(k): Device Modification as described in FDA's guidance document entitled "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications." In support of this 510(k), TeleMed Systems, Inc. has provided certification of compliance to 21 CFR 820.30 Design Control requirements, and a description of the internal Risk Analysis procedure. Performance testing conducted in support of this submission included balloon burst testing, pressure vs. diameter confirmation and scope passage testing.

Conclusion:
Based on the indications for use, technological characteristics, performance testing results and comparison to predicate devices, the TeleMed Systems, Inc. PPD™ Balloon Dilatation Catheters have been shown to be safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 6 2002

Mr. Michael Carroll
President & CEO
TeleMed Systems, Inc.
8 Kane Industrial Drive
HUDSON MA 01749

Re: K020379
Trade/Device Name: PPD™ Balloon Dilatation Catheter
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Product Code: 78 KNT
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary catheter and accessories
Product Code: 78 FGE
Regulatory Class: II
Dated: April 4, 2002
Received: April 8, 2002

Dear Mr. Carroll:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SPECIAL 510(k) PREMARKET NOTIFICATION: DEVICE MODIFICATION

510(k) Number (if known): K020379

Device Name: TeleMed Systems, Inc. PPD[tm] Balloon Dilatation Catheter

Indications for Use:

The TeleMed Systems PPD™ Balloon Dilatation Catheter is indicated for use in dilatation of gastrointestinal strictures of various etiologies (inflammatory, neoplastic, congenital, anastomotic) involving the esophagus, pylorus, biliary tract, sphincter of Oddi and colon.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020379

Prescription Use ✓ OR Over-the -Counter Use ____
(Per 21 CFR 801.109)