

OCT 25 1999

K993341

## Attachment 4

### 510(k) Summary

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#### SAFETY AND EFFECTIVENESS SUMMARY

This information of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

<b>Submitted by Name/Address:</b>	Chester McCoy Regulatory Affairs Engineer Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, UT 84095 (801) 253-1600 ext. 404 (801) 253-1684 fax
<b>Contact Person:</b>	Same as above
<b>Date Summary Prepared:</b>	September 15, 1999
<b>Device Name:</b>	IntelliSystem II Angioplasty Inflation Device
<b>Common Name:</b>	Monitor for an Angioplasty Inflation Device
<b>Trade Name:</b>	IntelliSystem II
<b>Classification (if known):</b>	Class II, 74 MAV.
<b>Predicate Device:</b>	K884913, INTELLIFLATOR™

**Performance Standards:**

Performance standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act.

**Device Description:**

The Merit Medical IntelliSystem comprises a disposable inflation/pressurizing syringe with an integral pressure transducer, an electronic monitor for displaying and storing data which is connected to the syringe via a disposable interface cable, a printer for producing a hard copy of data collected during the procedure, and mounting accessories with which the monitor is attached to the procedure table or an IV pole.

**Intended Use and Description:**

The INTELLISYSTEM II COLOR MONITOR displays pressures created by the INTELLISYSTEM25 Syringe which is used to pressurize the balloon of a dilation catheter during interventional procedures as well as monitor injectate pressures in various areas of the body. The INTELLISYSTEM25 Syringe is connected to the Monitor via two flexible four foot cables.

In addition to displaying pressure parameters in ATM, psi, mmHg, BARS, or kPa. The INTELLISYSTEM II MONITOR displays pressurization number, duration of pressurization in minutes and seconds, time elapsed since last pressurization, and when a negative pressure has been reached. The Monitor also has the capability to display all of the above functions while graphing the pressure cycle on the screen.

**Biocompatibility:**

The INTELLISYSTEM II COLOR MONITOR does not come into contact with the patient.

**Summary of Substantial Equivalence:**

The INTELLISYSTEM II COLOR MONITOR is substantially equivalent to the previously cleared INTELLIFLATOR MONITOR.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 25 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Chester McCoy  
Regulatory Affairs Engineer  
Merit Medical Systems, Inc.  
1600 West Merit Parkway  
South Jordan, UT 84095

Re: K993341  
Trade Name: IntelliSystem II Color Monitor  
Regulatory Class: II  
Product Code: MAV  
Dated: September 27, 1999  
Received: October 5, 1999

Dear Mr. McCoy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation

you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally, 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. 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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Wolf Sapirstein, M.D.  
Acting Director  
Division of Cardiovascular,  
Respiratory and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Attachment 2

### Indications for Use Statement

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510(k)  
Number  
(if Known)

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Device Name            IntelliSystem II Angioplasty Inflation Device

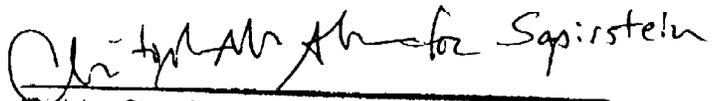
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Indications for Use    The Merit Medical INTELLISYSTEM II MONITOR is for use only with the disposable INTELLISYSTEM25 Syringe. It may be used to monitor the pressure of interventional devices as well as measure injectate pressures in various areas of the body.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number           K993341          

Prescription Use   X  

OR

Over-The-Counter Use \_\_\_\_\_