SEP 2 3 1997

K963071

Liebel Flarsheim Company

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Angiomat Illumena Injector 510(k) Summary

September 19, 1997

Official Contact:

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Classification Name:

Cardiovascular Diagnostic Device
per CFR 870.1650

Common/Usual Name:

Injector System

Proprietary Name:

Angiomat Illumena

Predicate Devices:

Angiomat 6000 (K860204)
CT 8000/9000 Injector (K912944)

Device Description:

The Angiomat Illumena is designed to inject a radiopaque contrast medium into the vascular system for Angiographic or CT procedures as prescribed by qualified health care professionals. The system is designed to be configured as either an Angiographic injector or as a CT injector.

The system includes a microprocessor controlled DC servo motor which drives a lead screw ram against the piston of a single use syringe. The operation of the servo is programmed by the operator using a touch screen on an electrolumenscent display. The system is powered by AC line voltage at 100 Volts, 120 Volts, or 240 Volts. System power is less than 1500 Watts.

A typical Angiomat Illumena system includes a power pack, console, powerhead, syringe holder assembly, ac power cable assembly, start cable assembly, and console cable assembly. Other options include ECG trigger systems, syringe heater, air detection and warning system, pedestal mounting system, wall/rack/ceiling mounting systems, interface cabling, powerhead and console extension cabling, start switch variations, and printer system.

The system is designed to deliver contrast from either a prefilled syringe or an unfilled syringe which is filled at the start of the procedure. A reusable, sterilizable syringe is also available.

The system will interface with an X-ray system allowing either the start of injection initiated by the X-ray system or start of X-ray initiated by the injector.

Major Component Descriptions:

Power Pack (Control Module) - The power pack is the center of the injection system. It communicates with the console (s) and powerhead to receive the user inputs then provides appropriate motor power/control to the powerhead and monitors injection performance in real time. It houses the main circuit breaker, DC power supply, main control PC board, communications PC board, and the servo system. It may also accept plug in options such as the simulated display ECG. All cabling terminates at the power pack.

Console - The console displays graphic and text prompts to the user and reads user responses via a touch screen while communicating with the power pack. It also incorporates a system remote On/Off switch. Within the console are the display, touchscreen, and console CPU PC board. It may also accept the optional dynamic display ECG PC board. The injection system may use either 1 or 2 consoles.

Powerhead - The powerhead actuates the 150ml or 125ml syringes with the assistance of the appropriate syringe holder assembly while communicating with the power pack. It allows both electronic and mechanical syringe filling/expelling then performs powered injections while displaying syringe and programmed parameter status on a display. Readiness is indicated via an illuminated lens. Within the powerhead are the motor/encoder, gear train, drive screw & ram, ram position sensor, fill/expel control, display, tilt sensor, syringe size detection sensors, syringe holder locked sensor, and powerhead control PC board. An optional syringe heater may also be installed.

Features:

Customized Display - the user may configure console display to only show the control functions that are desired.

Injection Mode - the user may select from 4 modes: angio-cardiac, angio-peripheral, auto-repeat, or CT. These modes set up the console display with the typical functions and parameter ranges for that mode. The angio-cardiac mode sets up the display with the minimum number of programmable functions while allowing the user to add functions if desired. The angio-peripheral mode sets up the display with the maximum number of programmable functions while allowing the user to remove functions if desired. The auto-repeat mode will allow the user to set up the injector to continuously repeat an injection automatically until a programmed total time has been achieved, with a programmed interval, (inject interval), between the injections. The CT mode sets up the display with the typical programmable functions for CT procedures and limits the flow rate and pressure limit to ranges that are typical for CT injectors.

Programmable Parameters - the user may enter injection parameters typical to either angiographic or CT injectors; flow rate, volume, rate rise, injection duration, inject delay, x-ray/scan delay, pressure limit, multiphasic injections, and inter-phase delay.

Real Time Display - the console displays the delivered volume and injection elapsed time in real time, the powerhead displays the volume remaining within the syringe.

Achieved Parameters - after each injection the console will display the achieved flow, volume, and pressure.

Stored Protocol - the user may program and store up to 99 injection protocols into the injector's injection library for convenience.

Multiphasic Injection - the user may program up to 4 phases to each injection

Inject Delay - the user may program the time that elapse from when the x-ray is started until the injection is started.

X-Ray Delay - the user may program the time that elapse from when the injection is started until the x-ray is started.

Inter-Phase Delay - the user may program the delay time between the phases of a multiphasic injection. This delay time is added to the end of the highlighted phase.

Inject Interval - the user may program the delay time between injections while in the auto-repeat mode.

Prefill Size - when the user installs the 125ml syringe holder assembly the user may use a prefilled syringe. The user must then select the prefilled volume: 50ml, 65ml, 75ml, 100ml, or 125ml. The injector then makes the necessary electronic conversions to accurately display the syringe volume.

Console Operation - the console display screens incorporate extra large primary parameter numbers, (flow & volume), for long range visibility. All user input is guided with prompts and highlighted button look a like graphics. User mistakes are guided with corrective actions. The four injection modes and customizing displayed functions assist in minimizing screen clutter.

Fill/Expel Control - the fill/expel control is a lever that will expel fluid if rotated towards the tip of the syringe and will fill the syringe when rotated away from the syringe tip. The degree that the knob is rotated determines the fill/expel flow rate. There is a detent in the fill direction that indicates the optimum fill rate. (the typical maximum fill flow rate without generating a significant amount of air bubbles within the syringe).

Powerhead Tilt Sensing - the angle of the powerhead is continuously monitored for safety reasons. When the powerhead is positioned with the syringe tip upward the injector may not perform a programmed injection, may fill/expel at the maximum fill/expel flow rates, and the powerhead display is oriented in the normal reading direction. When the powerhead is rotated down to the injection position the injector may perform a programmed injection, the fill/expel flow rate range is reduced, and the powerhead display is rotated 90 degrees to the appropriate reading orientation.

Intended Use:

The Angiomat Illumena is designed to inject a radiopaque contrast medium into the vascular system for Angiographic or CT procedures as prescribed by qualified health care professionals.

Product Features Compared to Predicate Devices:

Characteristic/ Feature	Angiomat 6000 (predicate device) (K860204)	CT9000 (predicate device) (K912944)	Angiomat Illumena (new device)
Multiphase Operation	9 phases per protocol	4 phases per protocol	4 phases per protocol
Protocol Storage	99 phases	12 protocols	99 protocols
X-ray/Scan Delay	0-255 sec	0-99 sec	0-300 sec
Inject Delay	0-255 sec	none	0-300 sec
Inter-phase Delay	none	0-99 sec	0-300 sec
Inject Interval	none	0-99 sec	0-300 sec
Syringe System	260 ml, 150 ml, or 125 ml	200 ml or 125 ml	150 ml or 125 ml
Volume Remaining Display	Mechanical scale on powerhead	Mechanical scale on powerhead	LCD display on powerhead
Fill Rate	3 to 25 ml/sec	2 to 7.2 ml/sec	3 to 25 ml/sec
Flow Rate	0.01 to 40 ml/sec for 125/150 ml syringe 0.01 to 59 ml/sec for 260 ml syringe	0.1 to 7.2 ml/sec for 200 ml syringe 0.1 to 4.9 ml/sec for 125 ml syringe	0.01 to 40 ml/sec for 125/150 ml syringe
Pressure Limit	100 to 1200 PSI	25 to 300 PSI	75 to 1200 PSI
Remote Start Switch	Yes	Yes	Yes

Performance Test Data and Conclusions:

A comprehensive set of tests were performed to verify that the programmed flow rate, volume, duration, pressure limit, and injection/X-ray delay performance are to specification. These tests demonstrate performance to specification within ranges equivalent to the predicate devices with accuracy and precision superior to the predicate devices.

Tests were performed using extremes of operating parameters to assure operation to specification for all conditions of operation.

Fluid Delivery Performance:

The volume delivery accuracy is validated by executing injections with water throughout the operating range of the injector. The delivered volume is measured accurately via calibrated equipment and compared to the programmed volume and achieved volume displayed by the injector. Performance meets product specifications for the Angiomat Illumena.

The pressure limit accuracy is validated by executing injections with water throughout the operating range of the injector. For each test the water flow is restricted to develop back pressure. This back pressure is accurately measured via calibrated equipment and then compared to the programmed pressure limit value and the achieved pressure limit value displayed by the injector. Performance meets the product specification for the Angiomat Illumena.

The flow rate delivery accuracy is validated by executing four steps. The first step is to verify that the algorithm for determining and displaying the flow rate is correct. The second step is to verify via measurement equipment that the injector servo electronics is accurately keeping time. The third is the volume validation step listed above. This step verifies that the entire drive system, (software, electronics, motor, encoder, gear reduction/transmission, drive screw, and syringe), is being correctly incremented by the injector electronics. The fourth step is to execute injections with water throughout the operating range of the injector. For each injection the achieved flow rate value, as determined by the injector, is recorded and compared to the product specification for the Angiomat Illumena.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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SEP 23 1997

Ms. Bridget Drake
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P.O. Box 156305
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Re: K963071
Angiomat Illumena
Regulatory Class: II (two)
Product Code: 74 DXT
Dated: July 3, 1997
Received: July 7, 1997

Dear Ms. Drake:

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 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 (Premarket 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 requirement, 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) 594-4639. 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 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/dsmamain.html".

Sincerely yours,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K963071

Device Name: ANGIOMAT ILLUMENA

Indications For Use:

The Angiomat Illumena is designed to inject a radiopaque contrast medium into the vascular system for Angiographic or CT procedures as prescribed be qualified health care professionals.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K963071

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)