K970344

AUG

510(k) SUMMARY

Device Trade Name	MDILog, Model MDC-511
Common Name:	Monitoring accessory for Metered Dose Inhalers
Classification Name:	Unknown, but accessory to metered dose inhalers which are classified as nebulizers

Contact Person: Linda Nelson
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12364 Alameda Parkway
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303-985-0252

Date Prepared: January 27, 1997

Substantial Equivalence Statement: MDILog is substantially equivalent to the predicate devices NewMed Doser (K935955), Medtrac Peaklog (K940835) and Nebulizer Chronolog (K823423).

Description: The MDILog system monitors the compliance of asthma and chronic respiratory patients with metered dose inhalers (MDIs) and allows the physician to assesses patients' technique in using MDIs. The system consists of the MDILog electronic monitor, an adapter, a docking station to communicate to an IBM compatible personal computer, and software. The MDILog monitor is a small electronics module operating on a 3-volt battery that attaches to the dispensing boot of a metered dose inhaler (MDI). It records the time and date when a patient uses an MDI, measures certain properties of the patient's technique, and transmits these data to a docking station, which transmits the data to a computer.

Intended Use : The MDILog system monitors the compliance of asthma and chronic respiratory patients with metered dose inhalers (MDIs) and allows for the physician to assess patients' techniques in using MDIs. The MDILog is intended for outpatient use by a single individual under the care or treatment of a physician or licensed health care professional. The device is to be used whenever patient compliance monitoring is indicated. The health care professional prescribes the patient medication treatment plan and MDILog monitors and records MDI medication usage.

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The summary of technological characteristics of this new device compared to predicate devices is described in the matrix in *Table of Comparison to Legally Marketed Devices* included in this section.

The tests that supported the determination of substantial equivalence were performance testing in a simulated-use condition, environmental tests, and software validation testing. These tests are in accordance with the Reviewer Guidance for Premarket Notification Submissions, Anesthesiology and Respiratory Device Branch and the Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(K) Review.

Table of Comparison to Legally Marketed Devices

Characteristic	Nebulizer Chronolog System (K823423)	PeakLog System (K940835)	Doser (K935955)	MDILog System
Intended Use	Monitor medication usage and compliance.	Measures spirometric functions and monitors compliance.	Monitor medication usage.	Monitor medication usage and compliance.
Principle of Operation	MDI canister placed in Chronolog body. Mechanical switch used to detect canister actuation. Data stored in device memory for later retrieval.	Hot wire technology used to detect air flow & firmware algorithms used to extrapolate measurements. Data stored in device memory for later retrieval.	Attaches onto MDI canister in dispenser. Pressure activated when the Doser is pushed down thus pushing the MDI to dispense medication. Counts stored in device memory	Attached onto outside of dispenser body. Heated thermister used to detect air flow, mechanical beam with strain gage used to detect canister actuation and moving magnet used to detect shake. Data stored in device memory for later retrieval.
Output Port and Computer Interface	Direct connection to stand-alone hardware via etched card and socket.	RS232 connector and interface cable	None	Infrared cells to Infrared reader Docking Station and interface cable.
Data Collection	Records data and time of each MDI canister actuation.	Measures PEFR and FEV1. Records date and time of each measurement.	Records number of MDI canister actuations.	Records date and time of shake, canister actuation and inhale.
Internal Clock	Yes (4 minute resolution)	Yes (1 second resolution)	Yes (30 minute resolution)	Yes (1 second resolution)
Digital Display	None	Yes (2 X 16 LCD)	Yes (1 X 6 LCD)	Yes (2 X 8 LCD)
Keyboard	None	Yes (4 key membrane switch)	Yes (2-push buttons, 1-pin set button)	Yes (2 key membrane switch)
Memory Size	8K	64K	Unknown	8K
Maximum Maneuvers Stored	256	500	300 (approximately)	1300
Power Source	3 - 1.4 volt zinc-air cells (User replaceable)	2 AAA alkaline batteries (User replaceable)	Battery (Non-replaceable)	1 - 3 volt lithium cell (Factory replaceable)
Battery Life	Over 1 year	4 weeks	1 year	Six months
Low Battery Indicator	None	Yes (message on display)	Yes (message on display)	Yes (message on display)
Patient Reminder	None	Yes - Beeps (reminds patient when to perform a measurement)	Yes - Beeps (reminds patient when 20 doses are left in canister)	Yes - Beeps (reminds patient when to take medication and when canister is empty)
Auto Power Saver	Yes	Yes	Yes	Yes
Support Software	Yes (stand-alone hardware)	Yes (IBM compatible)	None	Yes (IBM compatible)
Device Initialization and Re-initialization w/ Software	Yes	Yes	No	Yes
Patient Data Storage w/ Software	Yes	Yes	No	Yes
Patient Data Report	Yes	Yes	No	Yes

Characteristic	Nebulizer Chronolog System (K823423)	PeakLog System (K940835)	Doser (K935955)	MDILog System
Generation w/ Software				
Patient Data Graphs Generation	No	Yes	No	Yes
Data Retrieval from Device w/ Software	Yes	Yes	No	Yes
Read and report battery level w/ Software	Yes	Yes	No	Yes
Size	4 L X 2.5 W X 1.5 D (inches)	3 L X 2 W X 1 D (inches)	1.4 inch diameter	1.8 L X 1.1 W X 0.85 D (inches approximately)
Case Material	Carbon-filled polypropylene	K-resin (KR01)	Plastic (unknown)	Isoplast (2510)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Ms. Linda Nelson
Medtrac Technologies
12364 W. Alameda Parkway, Suite 115
Lakewood, Colorado 80228

AUG - 6 1997

Re: K970344
MDILog, Model MDC-511
Regulatory Class: II (two)
Product Code: 73 CAF
Dated: May 6, 1997
Received: May 8, 1997

Dear Ms. Nelson:

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 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) 594-4648. 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): K970344

Device Name: MDILog, model MDC-511

Indications For Use:

The MDILog is intended for use by a single patient under the care or treatment of a physician or licensed health care professional. The MDILog is prescribed by the doctor when detailed MDI usage monitoring is indicated. The MDILog can be used by any patient who regularly uses MDIs as prescribed by a physician.

It will be the physician or health care professional's responsibility to contact and coordinate with Medtrac Technologies the attachment of the MDILog adapter and device onto the MDI actuator. MDIs with attached MDILog adapters and devices will be distributed to patients by a physician or health care professional.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jo A Watershaus

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____

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

(Optional Format 1-2-96)