

SEP 24 1997

K971256

510(k) Summary

April 2, 1997

1. **Submitter:** Air-Shields, Inc.
330 Jacksonville Road
Hatboro, PA 19040
215-675-5200
Contact: Marci L. Goldfinger

2. **Device Trade Name:** Duo-Lite™ Phototherapy System
Device Classification Name: Neonatal Phototherapy Unit
Device Common Name: Phototherapy Unit

3. **Predicate Devices:**
The Air-Shields DUO-LITE™ Phototherapy System, Air-Shields Micro-Lite™ Phototherapy System, Air-Shields Fluoro-Lite® Phototherapy Unit, Ohmeda Spot Phototherapy Lamp, Olympic 66 and 33, and Drager PT4000.

4. **Device Description:**
The DUO-LITE™ Phototherapy System provides light output for maximum absorption by the infant's skin in order to reduce bilirubin levels. The DUO-LITE™ is designed for use in conjunction with a variety of other products. Perhaps the most common application is when placed on the hood of an incubator, or fitted to a rail system and positioned over the hood of the incubator. The DUO-LITE™ can also be mounted to a mobile stand, thus extending its applications to use with Open Warmers and Open Bassinets.

The product is L 23 x W 10 x H 5 (inches) and weighs approximately 15 Lbs. It is available in 100, 120 and 220/240V 50/60 Hz. The DUO-LITE™ is comprised of three 75W quartz halogen bulbs. The light emitted from these bulbs is filtered through IR/UV and Dichroic filters. The output of the bulbs is dependent on the driving voltage which is regulated by the internal power supply.

The user can select the use of White light or Blue light using the selector switch on the front of the lamp housing. The different color lights give different therapeutic outputs depending on the individual needs of the patient. Adjacent to the On/Off switch is a digital counter which can be set to display exposure time and bulb life remaining.

The DUO-LITE™ uses quartz halogen technology since the irradiance remains constant over the life of the bulb. By way of comparison, fluorescent bulbs degrade rapidly over the course of time and as such need to be continually monitored to ensure the output is therapeutically acceptable.

5. Statement of Intended Use:

The DUO-LITE™ Phototherapy System is designed to provide treatment in the form of Phototherapy to those infants that have been identified as having elevated bilirubin levels (hyperbilirubinemia). Phototherapy as a means for reducing bilirubin levels is a well established treatment modality. The output of the light has been optimized for maximum absorption by the skin in order to reduce the bilirubin levels as quickly as possible.

The DUO-LITE™ Phototherapy System provides the option to select white or blue light via a selector switch. This provides the caregiver with the option to give high output phototherapy for some infants (or early in the treatment cycle) followed by more moderate phototherapy for other infants (or later in the treatment cycle). By contrast, other phototherapy lamp products give the option of either White or Blue light which needs to be set up by an engineer in advance of the treatment. The DUO-LITE™ has combined these two light sources into one housing for the convenience of the caregiver.

The DUO-LITE™ Phototherapy System can be placed on the hood of an infant incubator, mounted on the Air-Shields Rail System, or positioned over an open warming bed or crib.

6. Comparison Matrix: Refer to Figure #1

7. Discussion of Non-clinical tests submitted:

Submitted in the 510(k) is a report on the spectral irradiance measurements conducted by an outside test house on the Duo-Lite™ Phototherapy System. The spectral irradiance was measured and recorded from 250 to 1100nm for the following configurations:

Filter Color	Voltage	Distance
Blue	120V	17"
Blue	132V	17"
White	120V	17"
White	132V	17"
Blue	120V	15.75"
Blue	132V	15.75"
White	120V	15.75"
White	132V	15.75"

The results were as expected for a device of this type across this bandwidth and also indicate low UV and IR output. Mattress mapping done in our in-house laboratory support our peak irradiance specifications. The data supports our claim of substantial equivalence to similar phototherapy devices already on the market.

Air-Shields Duo-Lite™ Phototherapy System
510(k) Summary

Product Comparison Matrix

Product Feature	Air-Shields DUO-LITE™	Air-Shields Micro-Lite®	Air-Shields Fluoro-Lite®	Ohmeda Spot PT Lamp	Olympic Model 66	Olympic Model 33	Drager PT 4000
Type	Freestanding	Freestanding	Freestanding	Freestanding	Freestanding	Freestanding	Freestanding
Size (inches)							
Height on Stand	55 - 65	55 - 65	38.5 - 56	57 - 91	49 - 65	42 - 61	42 - 64
L x W	21 x 17	21 x 17	27 x 13	12 x 6.25	26 x 11	25 x 19	21.3 x 11.2
Weight (on stand)	66 Lbs	56.5 Lbs	86 Lbs	40 Lbs	54 Lbs	52 Lbs	45.7 Lbs
Angle Adjustment	0 - 45°	0 - 45°	+/-90°	Multi Directional	0 - 90°	0 - 60°	0 - 30°
Irradiance (400 - 520 Nm)	≥10 (White) ≥20 (Blue) μW/cm ² /nm @ 43 cm	>9μW/cm ² /nm @ 43 cm	>12μW/cm ² /nm @ 39 cm	4 - 20 μW/cm ² /nm	4 - 9 (White) 4 - 20 (Blue)	4 - 9 (White) 4 - 20 (Blue)	>13μW/cm ² /nm @ 40 cm
Bulb							
Type	Quartz Halogen	Quartz Halogen	Fluorescent	Quartz Halogen	Fluorescent	Fluorescent	Fluorescent
Number	3 x 75W	3 x 50W	4 x 20W	1 x 250W	4 x 20W	8 x 20W	6 x 20W
Life	1,000 Hrs	1,000 Hrs	500 Hrs	500 Hrs	200 Hrs	200 Hrs	1,000Hrs
Color	Blue or White	White	Blue and/or White	White	Blue and/or White	Blue and/or White	Blue
Procedure Timer	Yes	Yes	Optional	No	Optional	Optional	Yes
Line Voltage	120 Vac	120 Vac	120 Vac	115 Vac	115 Vac	120 Vac	110 - 115 Vac
Power Consumption	350W	300W	140W	80 - 100W	160 - 180W	160 - 180W	120W
Leakage Current	<300μA	<100μA	<100μA	<100μA	<100μA	<100μA	<300μA
Communication Port	Yes	No	No	No	No	No	No

FIGURE #1



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 24 1997

Ms. Marci L. Goldfinger
Director, Quality Assurance and Regulatory Affairs
Air Shields, Incorporated
330 Jacksonville Road
Hatboro, Pennsylvania 19040-2211

Re: K971256
Trade Name: Duo-Lite Phototherapy System
Regulatory Class: II
Product Code: BLI
Dated: July 10, 1997
Received: July 11, 1997

Dear Ms. Goldfinger:

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 (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 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 pre-market 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) 594-4618. 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,



Timothy A. Ulatowski
Director

Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

. Enclosure

510(k) Number (if known): K971256

Device Name: Duo-Lite™ Phototherapy System

Indications For Use:

The DUO-LITE™ Phototherapy System is designed to provide treatment in the form of Phototherapy to those infants that have been identified as having elevated bilirubin levels (hyperbilirubinemia). Phototherapy as a means for reducing bilirubin levels is a well established treatment modality. The output of the light has been optimized for maximum absorption by the skin in order to reduce the bilirubin levels as quickly as possible.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Van KASIMIAN MD
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number _____

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

