K 963481

510(K) SUMMARY
(as required by 807.92(c))

AUG 1 1 1997

Submitter of 510(k):

Regulatory & Marketing Services, Inc. (RMS)
40178 U.S. 19 North
Tarpon Springs, FL 34689

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Date of Summary: August

Trade Name: Heyer America® Anodyne™ CC

Classification Name: Gas Machine for Anesthesia, 21CFR section 868.5160

Predicate Device:

K882484	Modulus II Plus	Ohmeda
K930351	Narkomed 2C	North American Drager

Device Description/ Comparison:

The HEYER America® Anodyne™ CC Anesthesia System is a standalone anesthesia device. The device is a reusable, non-sterile, life-supporting anesthesia machine for prescription use in hospitals, clinics and surgery centers.

The device is software driven. Adequate software testing with respect to the new IEC 601-1-4 has been conducted on the device. The device is electrically operated

Intended Use:

The Anodyne™ CC Anesthesia System is a device used to administer to a patient, continuously or intermittently, a general inhalation anesthetic and to maintain a patient's ventilation.

Answer to question #2 about the technology of the product.

Technology comparison

The HEYER America® Anodyne™ CC anesthesia system is a device that is used for the administration of anesthetic agents and gases, ventilatory patient monitoring and controlled respiratory ventilation.

The HEYER America® Anodyne™CC anesthesia system uses similar or identical technology and methods of operation as the legally marketed devices.

OHMEDA®	Modulus® II Plus	K 882489
North American Dräger®	Narkomed® 2C	K 930351

A detailed comparison of the technology used in the Anodyne CC anesthesia system and in the predicate devices follows for the different functions and features, including a comparison of non-clinical performance data.

Answer to question # 2 about the technology of the product.

Table of content

Answer to question # 2 about the technology of the product.

Technology comparison

Gas management

Similarities between the product and the predicate devices.

Cylinder yokes for PIN index E-cylinders allow the attachment of two O2, one N2O and 1 Air cylinder. The cylinder supply management contains filters at the cylinder gas inlet, check valves for the two O2 cylinder inlets to prevent bleeding of one cylinder, if the other yoke is not used, pressure regulators to reduce cylinder pressure downto the normal operating pressure and Bourdon type cylinder pressure gauges for each cylinder gas supply line.
Pipeline inlets with DISS connectors for O2, N2O, Air, Vac and Evac allow the attachment of central gas supply. Bourdon type pressure gauges indicate the pipeline pressure to the operator. A check valve arrangement for each gas provides the separation of cylinder and pipeline supply line.

The O2 supply line is checked for sufficient pressure level. When the O2 supply pressure drops below the specified minimum pressure level the O2 fail alarm device alarms the operator to the low O2 pressure.

In case the O2 supply pressure drops below the specified N2O-shut-off-O2-pressure-level, the N2O supply is shut off.

A main switch activates the device's gas supply.

Differences between the product and the predicate devices.

In the Anodyne CC patient and device is protected by water traps and particulate filters. In the predicate devices there are no built-in water traps. These are added as accessories.

In the Anodyne CC the O2 fail alarm operates pneumatically, using a pneumatic whistle. In the predicate devices the O2 fail alarm operates with an electrical alarm device delivering an alarm tone.

In the Anodyne CC the gas mix selector enables the operator to select one of four different Freshgas selections.

In a predicate device this selection is one of three.

Answer to question # 2 about the technology of the product.

Hypoxic guard

Similarities between the product and the predicate devices.

The O2/N2O mixture delivered in the Freshgas is generated from a hypoxic guard system providing a specified minimum percentage of oxygen.
The operator is not able to adjust a mixture below this minimum O2 concentration.
A minimum O2 flow is supplied to the Freshgas line, in case gas selections with N2O are made.

The combination of a specified minimum O2 flow and a hypoxic guard system provides an oxygen concentration dependent on the total Freshgas flow.
Between mid and high flows the O2 concentration stays at the minimum level as specified. For lower flowrates the O2 concentration increases upto 100 % when the minimum O2 flow is reached.

Differences between the product and the predicate devices.

The Anodyne CC uses a mechanical hypoxic guard system.
So does the OHMEDA device.
The NAD unit uses a pneumatic system.

Flowcontrol

Similarities between the product and the predicate devices.

The flowcontrol enables the operator to dose the gas flow precisely by changing the orifice of a valve.
The flowcontrol for each gas is mounted correspondent to the flowmeters.

An independent O2 flush allows a fast delivery of oxygen to the patient.

Differences between the product and the predicate devices.

None.

Answer to question # 2 about the technology of the product.

Flowmetering

Similarities between the product and the predicate devices.

The flowmeter set consist of two flowmeters for each gas with a fine and a coarse tube. The tubes are cascaded. Due to the overflow from fine to coarse the fine tube shows the specified values for the fine range and the coarse tube, beginning with the end of the fine tube range, shows the coarse range.
The flowmeter tube operate with the taper-cone-float system.

Differences between the product and the predicate devices.

None.

Vaporization

Similarities between the product and the predicate devices.

The vaporizer assembly is able to carry three vaporizers at a time with a safety function to enable only one vaporizer to work at a time.

The NAD device uses Dräger back entry type vaporizers. These back entry type vaporizers are mounted fixed to the vaporizer assembly and are not detachable. An exclusion system enables only one vaporizer to be operated at a time.

The OHMEDA device has a mounting system to carry detachable vaporizers of the Selectatec type. These vaporizers have a standardized mounting system for the gas connectors and the locking mechanism.
The mounting system on the device allows only vaporizers to adapt, that have an interlocking mechanism providing only one vaporizer to operate at a time.

The Anodyne CC can be equipped with either system, mentioned above.

Differences between the product and the predicate devices.

None.

Answer to question # 2 about the technology of the product.

Ventilator

Similarities between the product and the predicate devices.

The ventilator allows manual and controlled mandatory ventilation mode.

The ventilator is a time-cycled-flow-controlled type with pneumatic gas supply and electronic control.

The ventilator allows ventilation of pediatric and adult patients.

The ventilator has an adjustable pressure limiting function and a separate safety . pressure limiting valve.

The ventilator provides PEEP capabilities.

The ventilator activity is transferred to the patient gas circuit by a bellows assembly, contained within a cannister with clear plastic housing to view the bellows movement

Differences between the product and the predicate devices.

The NAD device allows the adjustment of I:E ratio, rate and flow. With these settings the ventilator creates a specific tidal volume as a resulting parameter.

The OHMEDA device allows the adjustment of rate, flow, an tidal volume. The I:E ratio is a dependent variable.

The Anodyne CC combines both systems in a way, that adjustments for I:E ratio, rate and tidal volume are allowed and the flow is a dependent variable.

Answer to question # 2 about the technology of the product.

Bellows

Similarities between the product and the predicate devices.

The bellows operates in a so called "bag in bottle" principle. A gas flow created by the ventilator powers the bellows housing and pressurizes the bellows inside.
The bellows transfers this activity onto the patient gas circuit, separating the two gas circuits by its membrane.

Differences between the product and the predicate devices.

The OHMEDA device uses bellows with two different sizes to match the different tidal volume ranges for pediatric and adult ventilation.

The NAD device uses only one bellows for both ventilation ranges.
So does the Anodyne CC.

NAD and OHMEDA use a separate ascending bellows assembly.
The Anodyne CC uses a descending one integrated inside the rebreathing circuit.

Absorber

Similarities between the product and the predicate devices.

An absorber system retaining the patients exhaled CO2 is installed, prepared for two prefill absorber container. The absorber canister allows the CO2 flow to move downstream.
The absorber canister is of transparent material to allow the operator to watch a color indicator inside the absorber material.

Differences between the product and the predicate devices.

The predicate devices have the absorber mounted as a separate component from the basic machine.
On the Anodyne CC the absorber is integrated inside the rebreathing system.

Answer to question # 2 about the technology of the product.

Rebreathing circuit / Patient module

Similarities between the product and the predicate devices.

The rebreathing circuit is a system to handle the gas going to and coming from the patient, representing the interface between basic gas machine and patient.

Inside the circuit directional valves control inspiratory and expiratory gas flow.

The rebreathing circuit allows the freshgas to flow to the patient with a blender type function between freshgas and rebreathing gas. Rebreathed gas flows to the CO2 absorber to retain the CO2 before it is blended with Freshgas.

A bag is connected to the rebreathing circuit to allow manual mode ventilation with an adjustable pressure limiting valve (APL) enabling the adjustment of the maximum airway pressure.

Differences between the product and the predicate devices.

The predicate devices have the absorber mounted as a separate component to the basic machine. Several connections to the basic machine for bellows, Freshgas and pressure measurement are necessary.
The predicate devices have the ventilator's bellows assembly mounted as a separate component to the basic machine. A connection between rebreathing / absorber system and bellows assembly is necessary.

On the Anodyne CC the absorber and the bellows assembly are integrated inside the rebreathing system. All connections to the basic machine are made inside the rebreathing system's docking station.

To prevent subatmospheric pressure effecting the patient the Anodyne CC allows room air to supply the rebreathing system in case a subatmospheric pressure is detected throug an "emergency air intake" valve.

To provide a fast pressure release in case of an accidental overpressure inside the rebreathing circuit the Anodyne CC provides an integrated Pop-off valve function.

Answer to question # 2 about the technology of the product.

Spirometry measurement

Similarities between the product and the predicate devices.

Flow measurement is performed to get information about the patient's expiratory tidal volume, minute volume and rate. The measured data are displayed to the operator to allow on-line control of ventilation efficiency.
Minimum alarm limits are adjustable to monitor the patient's tidal volume and/or minute volume activities.

Differences between the product and the predicate devices.

The NAD device displays the spirometry information in a separate monitoring display.
The OHMEDA device displays the spirometry data inside the ventilators display. So does the Anodyne CC.

The predicate devices use separate stand alone spirometry sensors, that need to be mounted either onto the rebreathing circuit (NAD) or inside the expiratory line (OHMEDA).
The Anodyne CC carries the spirometry sensor inside its rebreathing circuit.

Pressure measurement

Similarities between the product and the predicate devices.

Airway pressure measurement is performed to get information about the patient's airway pressure. Peak and PEEP pressure information is displayed numerically. A Bourdon type pressure gauge allows the operator to watch the pressure-time characteristic of the ventilation. Maximum and minimum pressure limits are adjustable to monitor the patient's airway pressure.

Differences between the product and the predicate devices.

The predicate devices also displays the pressure information in a separate monitoring display.
The Anodyne CC also displays the pressure data inside the ventilators display.

Answer to question # 2 about the technology of the product.

Oxygen measurement

Similarities between the product and the predicate devices.

Inspiratory oxygen concentration measurement is performed by a fuel cell type sensor mounted inside the inspiratory pathway.
The information is displayed numerically. Maximum and minimum oxygen concentration limits are adjustable to monitor the patient's inspiratory concentration.

Differences between the product and the predicate devices.

The NAD device displays the oxygen concentration information in a separate monitoring display.
The OHMEDA device displays the oxygen concentration data inside the ventilators display.
So does the Anodyne CC.

Answer to question # 2 about the technology of the product.

Performance comparison

Ventilator Performance

Parameter	Anodyne™ CC	Narkomed® 2C	Modulus® II Plus
Tidal volume range			
Total	50 - 1,400 ml	50 - 1,500 ml	50 - 1,500 ml
Pediatric	50 - 400 ml	50 - 300 ml	50 - 300 ml
Adult	300 - 1,400 ml	300 - 1,500 ml	300 - 1,500 ml
Frequency range			
Total	2 - 99 BPM	1 - 99 BPM	2 - 100 BPM
Pediatric	20 - 99 BPM	1 - 99 BPM	2 - 100 BPM
Adult	2 - 30 BPM	1 - 99 BPM	2 - 100 BPM
I:E Ratio range	1:3, 1:2, 1:1.5	1:4.5, 1:4, 1:3.5	dependent variable
	1:1, 2:1, 3:1	1:3, 1:2.5, 1:2	
		1:1.5, 1:1	
Insp. Flow Range	dependent variable	10 - 33 l/min	10 - 100 l/min
Insp. Pause	20%, 30%	-	25%
Sigh	1 of 100, 1.5 * Vt	-	-
Pressure limit range	10 - 100 cmH_2O	15 - 120 cmH_2O	20 - 100 cmH_2O

Answer to question # 2 about the technology of the product.

Airway Pressure Monitor Performance

Parameter	Anodyne™ CC	Narkomed® 2C	Modulus® II Plus
Pressure range	-10 - 100 cmH_2O	-10 - 70 cmH_2O	-20 - 120 cmH_2O
Real Time Graphics	Yes	Yes	No
Numerical values	P_{PEEP}	P_{PEEP}	P_{PEEP}
	P_{MEAN}	-	-
	P_{PEAK}	P_{PEAK}	P_{PEAK}
	$P_{PLATEAU}$	-	-
Alarm Messages	High	High	High
	Sustain	Sustain	Sustain
	Sub.	Sub.	Sub.
	Apnea	Apnea	Apnea
Alarm limits			
High	10 - 100 cmH_2O	10 - 70 cmH_2O	20 - 100 cmH_2O
Sustain	2 - 30 cmH_2O	10 - 30 cmH_2O	10 - 30 cmH_2O

Answer to question # 2 about the technology of the product.

Spirometer / Volume Monitor Performance

Parameter	Anodyne™ CC	Narkomed® 2C	Modulus® II Plus
Tidal volume range	20 - 9,999 ml	70 - 9,999 ml	0 - 9,999 ml
Breath rate range	0 - 99 BPM	3 - 50 BPM	0 - 99 BPM
Minute Volume range	0.1 - 999.9 l/min	0 - 999.9 l/min	0 - 999.9 l/min
Real Time Graphics	Yes	Yes	No
Numeric Values	Tidal volume	Tidal volume	Tidal Volume
	Minute volume	Minute volume	Minute volume
	Breath rate	Breath rate	Breath rate
Alarm messages	Tidal volume low	Tidal volume low	-
	Minute volume low	Minute volume low	Minute volume low
	Low rate	-	-
	High rate	-	-
Alarm limits			
Tidal v. Low	20 - 1,400 ml	70 - 1500 ml	-
Minute v.Low	0.5 - 5 L/min	0.5 - 10 L/min	0 - 9.9 L/min
Low rate	2 - 30 BPM	-	-
High rate	10 - 99 BPM	-	-

Answer to question # 2 about the technology of the product.

Oxygen Monitor Performance

Parameter	Anodyne™ CC	Narkomed® 2C	Modulus® II Plus
Concentration range	0 - 100 Vol%	0 - 100 Vol%	0 - 105 Vol%
Numeric value	Fio_2	Fio_2	Fio_2
Response time T90	15 sec	20 sec	15 sec
Sensor Life	12 months	12 months	12 months
Alarm messages	Low Fio_2	Low Fio_2	Low Fio_2
	High Fio_2	High Fio_2	High Fio_2
Alarm limits			
Low Fio_2	18 - 99 Vol%	18 - 99 Vol%	18 - 99 Vol%
High Fio_2	30 - 99 Vol%	18 - 99 Vol%	18 - 99 Vol%

Answer to question # 2 about the technology of the product.

Alarm Management Performance

Parameter	Anodyne™ CC	Narkomed® 2C	Modulus® II Plus
Central alarm panel	Yes	Yes	No
Central alarm silencer	Yes	Yes	No
Alarm silencer	60, 120 sec	60, 120 sec	individual
O2 fail alarm	audible	audible	audible

Data management Performance

Parameter	Anodyne™ CC	Narkomed® 2C	Modulus® II Plus
Type of interface	optical	galvanic	galvanic
Hardware protocol	IRDA	-	-
	RS 232 C	RS 232 C	RS 232
Bidirectional block	Yes	Yes	No

Answer to question # 2 about the technology of the product.

Gas management Performance

Parameter	Anodyne™ CC	Narkomed® 2C	Modulus® II Plus
Pressure gauges			
Pipeline	0 - 100 psig	0 - 100 psig	0 - 100 psig
Cylinder O2	0 - 3,000 psig	0 - 3,000 psig	0 - 3,000 psig
Cylinder Air	0 - 3,000 psig	0 - 3,000 psig	0 - 3,000 psig
Cylinder N2O	0 - 1,500 psig	0 - 1,500 psig	0 - 3,000 psig
High pressure regulators			
For each gas	Yes	Yes	Yes
Max. Input pressure	100 psig	100 psig	100 psig
Inlet connectors	DISS	DISS	DISS
Dual gas supply	manual	manual	manual
	automatic (option)	-	-
Pipeline operating range			
	45 - 55 psig	50 - 55 psig	50 psig
O2 supply failure alarm starts at			
	27 psig	27 psig	27 psig
N2O shut off at	24 psig	20 psig	20 psig
O2 flush	50 ± 10 lpm	55 ± 10 lpm	60 ± 15lpm

Answer to question # 2 about the technology of the product.

Flowmeter assembly Performance

Parameter	Anodyne™ CC	Narkomed® 2C	Modulus® II Plus
O2 double tube	0 - 1,000 ml/ min	100 - 1,000 ml/min	200 - 650 ml/min
	1.0 - 10 l/ min	1.0 - 10 l/ min	0.7 - 12 l/min
N2O double tube	0 - 1,000 ml/min	100 - 1,000 ml/min	20 - 650 ml/min
	1.0 - 10 l/min	1.0 - 10 l/min	0.7 - 12 l/min
AIR tube	double	double	single
	0 - 1,000 ml/min	100 - 1,000 ml/min	1 - 15 l/min
	1.0 - 10 l/min	1.0 - 10 l/min	-
Minimum O2 flow	250 +- 50 ml/min	250 +- 50 ml/min	200 ml/min
Hypoxic guard	25 Vol% O_2	25 Vol% O_2	25 Vol% O_2
Backlight	Yes	Yes	(Option)
O_2 knob	Touch code	Touch code	Touch code
Knob guard	Yes	Yes	Yes

Answer to question # 2 about the technology of the product.

Vaporizer Performance

Parameter	Anodyne™ CC	Narkomed® 2C	Modulus® II Plus
Maximum number of vaporizers to mount			
	3	3	3
Mounting system I.	Selectatec®	-	Selectatec®
Vaporizers to mount			
	OHMEDA® TEC® 4 TEC® 5 TEC® 6	-	OHMEDA® TEC® 4 TEC® 5 TEC® 6
	Penlon® PPV Elite®		Penlon® PPV Elite®
	Blease® Datum®		Blease® Datum®
	MIE® Vapamaster®		MIE® Vapamaster®
Interlock system			
	Yes	-	Yes
Mounting system II.	Back entry	Back entry	-
Vaporizers to mount			
	DRÄGER® Vapor® 19.1 Desvapor®	DRÄGER® Vapor® 19.1 Desvapor®	

Answer to question # 2 about the technology of the product.

Rebreathing Circuit Performance

Parameter	Anodyne™ CC	Narkomed® 2C	Modulus® II Plus
Mounting type	integrated	stand alone	stand alone
APL valve	Yes	Yes	Yes
APL range	2 - 50 cm H_2O	2 - 100 cm H_2O	1 - 75 cm H_2O
Canister capacity	3 lbs	3 lbs	3 lbs
Pre fill type	US	US	US
Exhalation port	22 mm taper	22 mm taper	22 mm taper
Inhalation port	22 mm taper	22 mm taper	22 mm taper
Bag nipple	22 mm taper	22 mm taper	22 mm taper
Excess gas outlet	19 mm OD	19 mm OD	19 mm OD
Ventilator connection	integrated	22 mm OD	22 mm OD
Circuit pressure sensing port	integrated	8 mm ID	8 mm ID
Common gas inlet	integrated	11 mm ID	11 mm ID
Oxygen sensor place	Inspiration valve	Inspiration valve	Inspiration valve

Answer to question # 2 about the technology of the product.

Clinical discussion

The HEYER America Anodyne CC anesthesia system is also based on the technology of a product series legally marketed in Europe and manufacturered by HEYER Anesthesia, such as:

Manufacturer	Model	Approval No.	Approval Date
HEYER Anesthesia	DOGMA®	09/M-015/94	05/11/1994
HEYER Anesthesia	ACCESS®	09/M-019/95	10/25/1995

Numerous units of these types are in clinics and hospitals inside Europe being used as anesthetic gas delivery machines.

Compared to the predicate devices these devices have proven over the years to have the same level of safety and efficiency in Europe where the predicate deives are also sold.

Conclusion

Basing on the technology comparison, the performance comparison and the clinical discussion we can confirm the HEYER America Anodyne CC to be as safe as and as effective as the predicate compared devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

AUG 11 1997

Mr. Ed Ransom
Heyer American, Inc.
C/O Regulatory & Marketing Services, Inc.
40178 U.S. 19 North
Tarpon Springs, Florida 34689

Re: K963481
Heyer America® Anodyne™ CC Anesthesia System
Regulatory Class: II (two)
Product Code: 74 BSZ
Dated: March 16, 1997
Received: May 19, 1997

Dear Mr. Ransom:

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

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): K963481

Device Name: Heyer America® Anodyne™ CC Anesthesia System

Indications For Use:

The Anodyne™ CC Anesthesia System is a device used to administer to a patient, continuously or intermittently, a general inhalation anesthetic and to maintain a patient's ventilation.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K963481

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

(Optional Format 1-2-96)