

K972138

**Carr Metal Products, Inc.**  
**3735 N. Arlington Ave.**  
**Indianapolis, IN 46218**

NOV 13 1997

**Non-Confidential Summary of Safety and Effectiveness**

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November 7, 1997

**Carr Metal Products, Inc.**  
**3735 N. Arlington Ave.**  
**Indianapolis, IN 46218**

**Tel - (317) 542-0691**  
**Fax - (317) 542-0694**

**Official Contact:** Alan Booker - Operations Manager  
**Proprietary or Trade Name:** Carr Sterilization Container System  
**Common/Usual Name:** Sterilization Container - rigid  
**Classification Name:** Sterilization wrap  
**Device:** Carr Sterilization Container system  
**Predicate Devices:** Aesculap - K792558, Medin - K833343, InstruMed - K844672  
and Riley - K871202

**Device Description:**

A rigid container system include a base available in several depth sizes ( 2.5", 3.0", 3.5", 4.0" and 5.0") and a lid which fits any of the bases. The lid is a standard size which fits any size (depth) of base, it also incorporates a filter retainer unit which holds a disposable filter, has a seal and incorporates a latching mechanism which latches the lid and base together.

**Indicated Use --** Container system designed to contain medical and dental (excluding dental hand pieces) instruments for sterilization, storage, and transportation. Suitable for Pre-vacuum steam and EO sterilization. Used and handled by healthcare personnel such as - central supply, operating room nurses, surgical nurses, dental assistants, or healthcare personnel who have responsibility for the cleaning, handling, sterilization and storage of medical and dental (excluding dental hand pieces) instruments.

**Environment of Use --** Used in health care facilities - hospitals, nursing homes, extended care facilities, free standing surgical centers, clinics and medical and dental offices. Within these facilities the setting may be where medical and dental (excluding dental hand pieces) instruments which are required to be sterile

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are utilized. Examples are - operating rooms - acute, sub-acute, outpatient surgery, physician and dental offices, wards, central services of a hospital.

**Summary of Performance Testing --**

The Carr Container system was independently tested according to AAMI ST 33, ANSI / AAMI ST 41-1992 and ST 24-1192 for its performance under two(2) sterilization methods - Pre-vacuum steam ( 270<sup>o</sup> - 275<sup>o</sup> F) and Ethylene Oxide (EO). It passed all criteria specific to sterilization containers and maintained a shelf life sterility of at least 30 days.

**Comparison to Predicate Devices:**

Attribute	Carr Container	Aesculap K792558 or other referenced predicates
<b>Use</b>		
Indicated for holding instruments	Yes	Yes
to be sterilized and stored	Yes	Yes
Intended to be reused		
Methods of sterilization - pre-vacuum steam (270 <sup>o</sup> F - 275 <sup>o</sup> F)	Yes	Yes
for a minimum of 4 minutes		
ethylene oxide follow sterilizer		
manufacturer's recommendations	Yes	Yes
Minimum 12 hours acration		
<b>Design</b>		
Various sizes(2.5, 3.0, 3.5, 4.0, 5.0") depth	Yes	Yes
of bases offered		
Incorporates a filter to permit entry		
of steriliant agent and prevent microbial	Yes	Yes
migration during storage		
Utilizes latch system to hold	Yes	Yes
lid in place		

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Attribute	Carr Container	Aesculap K792558 or other referenced predicates
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**Design**

Filter retainer does not have direct alignment holes preventing accidental puncture media of filter	Yes	No
Incorporates a silicone seal within lid	Yes	Yes
Utilizes trays to hold instruments in place	Yes	Yes
Has a tamper evident device slot	Yes	Yes
Outside labeling slot	Yes	Yes
Useful life subject to user handling and routine inspection after each use	Yes	Yes

**Performance Standards / Specifications**

AAMI ST 33-R-11/95 Standard testing and requirements	Yes	Claimed by Aesculap K792558
3.2 Permits transfer of contaminated materials	Yes	Claimed by Aesculap K792558
3.3.1 Removable filter assembly disassembles	Yes	On Aesculap K792558
3.3.4 Labeling - reusable labels	Yes	Claimed by IntsrMed K844672
3.4 - 3.5 Instructions provided for different cleaning methods	Yes	Assumed provided
3.6 - 4.2 Instructions for inspections	Yes	Claimed by Medin K833343, InstruMed K844672
6.2.2 Sterilization - manufacturer documentation available	Yes	Assumed
6.2.3 Drying time in labeling	Yes	Assumed
6.2.4 EO residual removal - in labeling	Yes	InstruMed K844672
6.2.5 Sterility maintenance - discussed in labeling, claimed in independent testing	Yes	

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<b>Attribute</b>	<b>Carr Container</b>	<b>Aesculap K792558 or other referenced predicates</b>
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<b>Performance Standards / Specifications</b>
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6.3 User (basic) responsibilities listed in labeling	Yes	Assumed
7.3.1 Routine inspection in labeling	Yes	Assumed
Testing of container under a challenge per ANSI / AAMI ST 41-1992 and ST24-1992 for prevacuum steam and EO sterilization	Passed	Claimed by Medin in literature - K833343
Claim of at least 30 days sterility shelflife supported by test data	Yes	InstruMed K844672
Validation study performed to determine that contents would be sterile utilizing prevacuum steam and ethylene oxide	Yes	Claimed by Aesculap K792558, Medin K833343

<b>Materials</b>
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Aluminum for lid and base	Yes	Yes
Coating for lid and base	Yes	Yes
Approved filter media	Yes	Yes

<b>Differences Between Other Legally Marketed Predicate Devices</b>
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There are no significant differences between the intended device and the predicate - Aesculap approved under K792558, Medin - K833343, InstruMed - K844672 and Riley - K871202.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Alan Booker  
Operations Manager  
Carr Metal Products, Incorporated  
3735 N. Arlington Avenue  
Indianapolis, Indiana 46218

NOV 13 1997

Re: K972138  
Trade Name: Carr Rigid Container System  
Regulatory Class: II  
Product Code: FRG  
Dated: September 5, 1997  
Received: September 8, 1997

Dear Mr. Booker:

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.

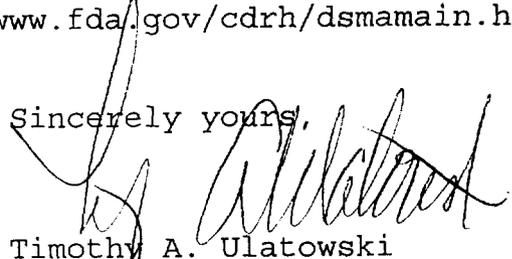
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

Page 2 - Mr. Booker

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) 594-4692. 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

**INDICATIONS FOR USE**

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**510(k) Number:** K972138**Device Name:** Carr Rigid Sterilization Container System**Intended Use :** Container system designed to contain medical and dental (excluding dental hand pieces) instruments for sterilization and storage. This device is intended to be used and handled by healthcare personnel. This container system is suitable for Pre-vacuum steam and EO sterilization. Sterility assurance tested up to 30 days.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*George S. Miller for Qin S. Lin Ph.D*

(Division Sign-Off)

Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number K972138

**Prescription Use** \_\_\_  
(Per CFR 801.109)

or

**Over-the-counter use** \_\_\_