

# Traditional 510(k) Premarket Notification Summary of Safety and Effectiveness

APR - 5 2011

K100262 p 1 of 2

**Submitter Information** Noble Marketing  
Jeff Baker  
President & CEO  
100 East Pine Street, Suite 305  
Orlando, FL 32801

**Contact Person** Allison Scott, RAC  
Regulatory Consultant  
317-569-9500 x106  
317-569-9520 (fax)  
ascott@ansongroup.com

**Date** March 30, 2011

**Trade Name** Sharps Container

**Common Name** Container, Sharps

**Classification Name** MMK

**Classification Number** 21 CFR 880.5570

**Predicate Devices** GongDong K082042 MMK 880.5570

**Device Description** The Noble Sharps Container are intended to be used at healthcare facilities, including nursing stations, medication carts, laboratories, emergency rooms, treatment rooms, and other small quantity waste generators for the safe disposal of hazardous sharps.

**Intended Use** The Noble Sharps container is a disposable over the counter sharps container that is intended for the safe disposal of used medical sharps. It is intended for use in offices, exam and patient rooms of small quantity healthcare providers such as medical doctors, dentists, and veterinarians. The size of the Sharps Container is 6 7/16" in height x 4 15/16" in width x 2 7/16" in depth. It is designed with 4- individual single use chambers with each holding 1-sharp, with a maximum sharp length of 6 1/8".

**Summary** The Nobles Sharps Container is a single use device designed for the safe disposal of hazardous sharps. It is designed with 4-chambers, each chamber will hold one sharps. After each chamber is filled with a sharp, a locking lid is closed by pressing downward, thus permanently sealing the sharps inside the container. All materials including the bottom, sides, and locking lid are manufactured using PP7726 (polypropylene) the same material used in the predicate device, the GongDong disposable sharps container cleared under K082042. The size of the Noble Sharps Container is 6 7/16" in height, 4 15/16" in width and 2 7/16" in depth. The Noble Sharps Container proves to be substantially equivalent to the predicate device.

**Comparison to Predicate Devices**

The Sharps Container is similar to the predicate in intended use, materials, measuring principle and performance.

	<b>Noble Sharps Container</b>	<b>GongDong Disposable Sharp Container</b>
510(k) Number	K100262	K082042
Product Code	MMK	MMK
Indication for Use	<ul style="list-style-type: none"> <li>• Single Use Healthcare Sharps</li> </ul>	<ul style="list-style-type: none"> <li>• Single Use Healthcare sharps</li> </ul>
Target Population	<ul style="list-style-type: none"> <li>• Healthcare professional</li> </ul>	<ul style="list-style-type: none"> <li>• Healthcare professional</li> </ul>
Where used	<ul style="list-style-type: none"> <li>• Healthcare facilities/labs</li> </ul>	<ul style="list-style-type: none"> <li>• Healthcare facilities/labs</li> </ul>
Construction	<ul style="list-style-type: none"> <li>• Injection molded</li> </ul>	<ul style="list-style-type: none"> <li>• Injection molded</li> </ul>
Materials	<ul style="list-style-type: none"> <li>• Polypropylene</li> </ul>	<ul style="list-style-type: none"> <li>• Polypropylene</li> </ul>
Lid	<ul style="list-style-type: none"> <li>• Closure by pressing down on lid secure</li> </ul>	<ul style="list-style-type: none"> <li>• Closure by pressing down on lid to secure</li> </ul>
Needle elimination	<ul style="list-style-type: none"> <li>• By vertical dropping</li> </ul>	<ul style="list-style-type: none"> <li>• By vertical dropping</li> </ul>

**Technological Characteristics**

Similar to other sharps containers on the market, sharps are inserted through the top in a vertical position with the sharp side down through the hole in which the sharp is inserted. A lid is then closed by pressing the lid downward for permanent closure and containment of sharps.

**Performance of Non-Clinical**

The Noble Sharps container subjected to puncture resistance testing per ASTM F 2132, topple resistance testing per CSA Z316.6-07, and leakage tests per BS 7320:1990. Noble Sharps Container proves to be substantially equivalent to currently marketed sharps containers.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room –WO66-G609  
Silver Spring, MD 20993-0002

Noble Marketing  
C/O Mr. Mark Job  
Responsible third party Official  
Regulatory Technology Services, LLC  
1394 25<sup>th</sup> Street NW  
Buffalo, Minnesota 55313

APR - 5 2011

Re: K110262  
Trade/Device Name: Sharps Container  
Regulation Number: 21 CFR 880.5570  
Regulation Name: Hypodermic Single Lumen Needle  
Regulatory Class: II  
Product Code: MMK  
Dated: March 24, 2011  
Received: March 25, 2011

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

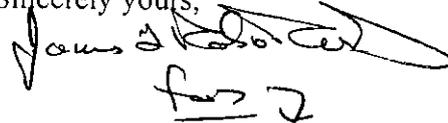
Page 2- Mr. Job

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.  
Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number: K110262

Device Name: Sharps Container

### Indications For Use:

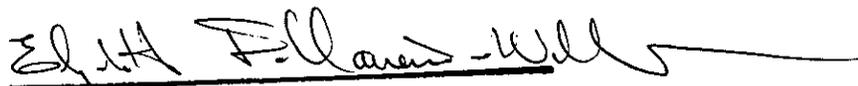
The Noble Sharps container is a disposable over the counter sharps container that is intended for the safe disposal of used medical sharps. It is intended for use in offices, exam and patient rooms of small quantity healthcare providers such as medical doctors, dentists, and veterinarians. The size of the Sharps Container is 6 7/16" in height x 4 15/16" in width x 2 7/16" in depth. It is designed with 4- individual single use chambers with each holding 1-sharp, with a maximum sharp length of 6 1/8".

Prescription Use \_\_\_\_\_ AND/OR Over-The-Counter Use  X   
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(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 Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number:  K110262