510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

Submitter's Name: $TANGO_3$, LLC

141A Citizens Blvd.

Simpsonville, KY 40067

Telephone: (502) 722-8794

DEC 8 2010

Contact person: Hugh Doss, Manager

Date of Summary: October X, 2009

Device Name: $TANGO_3$ Water Storage Tank with Ozone Disinfection System

Device Classification Name: Disinfectant, Dialysate Delivery System (876.5860, NII)

Device Description: The $TANGO_3$ Water Storage Tank with Ozone Disinfection System is specifically designed to facilitate ozone induction into the storage tank, and then distribute the ozonated water through the distribution water loop during non-operational hours of a hemodialysis facility. The storage tank of the $TANGO_3$ system is filled with adequate water and the ozone concentration is increased. The ozonated water is distributed throughout the distribution loop. The solution is recirculated throughout the distribution system. To complete the disinfection process, the system and distribution loop are then rinsed with adequate water. The described process is repeated three (3) more times. After the last cycle $TANGO_3$ will leave the system residual free of ozone.

To accomplish this, $TANGO_3$ has a corona discharge generator that generates ozone from a source of dry air. The air dryer consists of two heat regenerative desiccant modules. The ozone is injected into the tank by means of a venturi based injection system. Once in the tank, the ozonated water is sent to the distribution loop with a centrifugal pump. Ozone levels are monitored at the return of the loop. Two (2) flow sensors, located at the input and output of the distribution loop will assure that the dialysis facility is not utilizing water while ozone is present in the loop.

Intended Use: The $TANGO_3$ Water Storage Tank with Ozone Disinfection System is intended to be used for disinfection of the water distribution system of a dialysis facility. The tank of the $TANGO_3$ is also used as the water holding tank of the distribution system. The disinfection process is completely automated. Ozone concentration during disinfection is between 0.2 ppm and 0.3 ppm. The distribution system will be exposed to ozone for one (1) period of 45 minutes and three (3) subsequent periods of 30 minutes with adequate water flushes between them and at the end, leaving the distribution loop without ozone.

Legally Marketed Devices to which Equivalence is Claimed: The legally marketed predicate devices analysis was divided into 3 areas: intended use, technological characteristics, and operational features:

Devices with equivalent intended use:

- Minncare® (Minntech Corporation) and other Peracetic Acid products such as Renalin® (K830575) (Minntech Corporation) and Peracidin® (K962959) (AlcavisHDC) which are commonly used in hemodialysis clinics to disinfect the reverse osmosis water purification equipment and the water distribution loop
- Sodium hypochlorite at 500 ppm dilution is commonly used in dialysis facilities with soak times of 30 minutes.

Devices with equivalent intended use, technological characteristics and operational characteristics:

- O_3Z (K043207) - The O_3Z Ozone System is an optional accessory for the Solution Delivery Systems (SDS) manufactured by GE Infrastructure, Water & Process Technologies, and is intended to be used for disinfection of the SDS bicarb mixing and distribution system. This device and the bicarb distribution system have equivalent technological features with $TANGO_3$ and the water distribution loop, respectively. The O_3Z Ozone System disinfects with ozone and then flushes the system with adequate water after disinfection. Disinfection must be performed during non-operational hours just as $TANGO_3$.

Devices with equivalent intended use and operational characteristics:

- CWP 100 – WRO H (K974899) (heat disinfection unit for the distribution loop only) – The CWP 100 – WRO H has a heat disinfection unit that produces enough heat to disinfect the water in the water distribution loop. This disinfection process is automatic and usually performed during non-operational hours. The device has automatic flushing programs to be used when the system is not in use just as $TANGO_3$.

Descriptive Summary of Technological Characteristics and Those of Predicate Devices: The features of $TANGO_3$ are equivalent to those of other medical devices, systems or disinfectants currently in distribution in the United States with equivalent intended uses, technological characteristics, and operational characteristics.

Performance Data: Each function of the $TANGO_3$ System was tested to see if it performed as intended. Any errors or failures detected during testing were corrected. *In vitro* testing was also performed to validate the disinfection capabilities of $TANGO_3$ with waterborne organisms. All materials found in water distribution loops have been tested for material compatibility with ozone. A field test has been performed to validate that $TANGO_3$ can address the needs of facilities with known water contamination issues. The results from these tests show that the $TANGO_3$ performed as expected.

Conclusion: The information and data provided in this 510(k) Notification establish that the $TANGO_3$ Water Storage Tank with Ozone Disinfection System is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Lori Kleinschrodt Holder, RAC
Regulatory Affairs Consultant
TANGO$_3$, LLC
141A Citizens Blvd.
SIMPSONVILLE KY 40067

DEC 8 2010

Re: K093641
Trade/Device Name: TANGO$_3$ Water Storage Tank with Ozone Disinfection System
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: FIN
Dated: November 26, 2010
Received: November 30, 2010

Dear Ms. Holder:

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.

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,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

I. INDICATIONS FOR USE STATEMENT

November 23, 2010

510(k) Number: K093641

Device Name: $TANGO_3$ Water Storage Tank with Ozone Disinfection System

Indications for Use: The $TANGO_3$ Water Storage Tank with Ozone Disinfection System is intended to be used for disinfection of the water distribution system of a dialysis facility. The tank of the $TANGO_3$ is also used as the water holding tank of the distribution system. The disinfection process is completely automated. Ozone concentration during disinfection is between 0.2 ppm and 0.3 ppm. The distribution system will be exposed to ozone for one (1) period of 45 minutes and three (3) subsequent periods of 30 minutes with adequate water flushes between them and at the end, leaving the distribution loop without ozone.

(Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K093641

Prescription Use X OR Over-the-Counter Use ____
(Per 21 CFR 801.109)