



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

February 27, 2013

Mr. Harry Bala  
President  
Dana Products, Incorporated  
7 Corey Drive  
SOUTH BARRINGTON IL 60010

Re: K120592

Trade/Device Name: Dana Reusable Bowie Dick Type Pack and  
Dana Bowie Dick Indicators

Regulation Number: 21 CFR 880.2800

Regulation Name: Sterilization Process Indicator

Regulatory Class: II

Product Code: JOJ

Dated: February 15, 2013

Received: February 19, 2013

Dear Mr. Bala:

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.

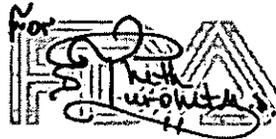
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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" (21 CFR 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,

A handwritten signature in black ink, appearing to read "Anthony D. Watson". The signature is stylized and somewhat cursive, with the first name "Anthony" being the most prominent.

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

Enclosure

## Indications for Use

K120592

510(k) Number (if known):

Device Name: Dana Reusable Bowie Dick Type Test Pack and Dana Bowie Dick Indicators

### Indications For Use:

The Dana Reusable Bowie Dick Type Test Pack, when used with a Dana Bowie Dick indicator, is designed for testing the air removal efficiency of pre-vacuum steam sterilizers. The indicator will demonstrate complete dye migration when proper sterilization conditions are met and proper vacuum is achieved. If there is inadequate vacuum such that would result in a 2°C (+1°/-0°C) temperature difference between the center of the ANSI/AAMI/ISO 11140-5:2007 Standard Test Pack and the drain temperature at the beginning of the final minute of a three and a half minute cycle, the indicator will demonstrate incomplete dye migration (incomplete color change in the indicator window). The test parameters used for validating this device were 134°C for 3.5 minutes with a 2 minute dry time.

Prescription Use \_\_\_\_\_ AND/OR  
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use  X   
(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)

Elizabeth F. Clavier

2013.02.25 17:26:13 -05'00'

Page 1 of 1

(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number:  K120592