



April 2, 2024

Medical Device Inspection Co., Inc.  
Alan P. Schwartz  
President  
55 Northern Blvd.  
Suite 301  
Great Neck, New York 11021

Re: K912104  
Trade/Device Name: Major Basin Tray  
Regulation Number: 21 CFR 878.4800  
Regulation Name: Manual surgical instrument for general use  
Regulatory Class: Class I  
Product Code: FSM

Dear Alan P. Schwartz:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated August 9, 1991. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code FSM.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Yu-Chieh Chiu, OHT4: Office of Surgical and Infection Control Devices, 301-796-6196, [yu-chieh.chiu@fda.hhs.gov](mailto:yu-chieh.chiu@fda.hhs.gov).

Sincerely,

**Yu-chieh Chiu -S**

Yu-Chieh Chiu, Ph.D.  
Assistant Director  
DHT4B: Division of Infection Control  
and Plastic Surgery Devices  
OHT4: Office of Surgical  
and Infection Control Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
1390 Piccard Drive  
Rockville MD 20850

MAY - 9 1991

Mr. Alan P. Schwartz  
President  
Medical Device Inspection Co., Inc.  
55 Northern Blvd.  
Suite 301  
Great Neck, New York 11021

Re: K912104  
Major Basin Tray  
Regulatory Class: Class I  
Dated: May 9, 1991  
Received: May 13, 1991

Dear Mr. Schwartz:

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 to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the devices, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). However, you are responsible to determine that the medical devices you use as components in the Major Basin Tray have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the Act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (unfinished) and further process (e.g. sterilize), you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (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 the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

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An FDA finding of substantial equivalence of your device to a pre-amendments device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your devices or their labeling as being approved by FDA. If you desire specific advice on the labeling for your devices please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-1116. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



David L. West, Ph.D.  
Deputy Director  
Office of Device Evaluation  
Center for Devices and  
Radiological Health