



October 27, 2022

AutoVage®
Joseph P. Rudolph, M.D.
1631 Citation Drive
Library, Pennsylvania 15129

Re: K922785
Trade/Device Name: IrriVage®
Regulation Number: 21 CFR 878.4014
Regulation Name: Nonresorbable Gauze/Sponge For External Use
Regulatory Class: Class I
Product Code: EYF

Dear Joseph P. Rudolph, M.D.:

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 October 16, 1992. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under regulation number, 878.4014.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Julie Morabito, OHT4: Office of Surgical and Infection Control Devices, 240-402-3839, Julie.Morabito@fda.hhs.gov.

Sincerely,

Julie A. Morabito -S

Julie Morabito, Ph.D.
Assistant Director for Plastic Surgery Skin
and Wound Devices
DHT4B: Division of Infection Control
and Plastic Reconstructive 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

OCT 16 1992

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

Joseph P. Rudolph, M.D.
AUTOVAGE®
1631 Citation Drive
Library, Pennsylvania 15129

Re: K922785
IrrivAge®
Regulatory Class: I
Dated: August 25, 1992
Received: August 28, 1992

Dear Dr. Rudolph:

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 device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

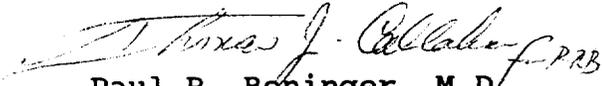
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market 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.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate 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 device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device, please contact the Division of

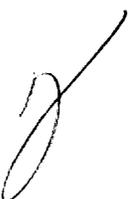
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Compliance Operations, Device Labeling Compliance Branch
(HFZ-326) at (301) 427-1342. Other general information on
your responsibilities under the Act, may be obtained from the
Division of Small Manufacturers Assistance at their toll free
number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Paul R. Beninger", with a small "P.R.B." written to the right of the signature.

Paul R. Beninger, M.D.
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

A large, stylized handwritten mark or signature in the bottom right corner of the page, consisting of a single, sweeping stroke that loops back.