List of Subjects in 21 CFR Part 878
Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, part 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

1. The authority citation for part 878 continues to read as follows:


2. Add § 878.4165 to subpart E to read as follows:

§ 878.4165 Wound autofluorescence imaging device.

(a) Identification. A wound autofluorescence imaging device is a tool to view autofluorescence images from skin wounds that are exposed to an excitation light. The device is not intended to provide quantitative or diagnostic information.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.


Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2018–22837 Filed 10–18–18; 8:45 am]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2018–N–3598]

Medical Devices; General and Plastic Surgery Devices; Classification of the Light Based Energy Source Device for Topical Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the light based energy source device for topical application into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the light based energy source device for topical application’s classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients’ access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective October 19, 2018. The classification was applicable on October 18, 2012.

FOR FURTHER INFORMATION CONTACT: Neil Ogden, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G414, Silver Spring, MD, 20993–0002, 301–796–6397, Neil.Ogden@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the light based energy source device for topical applications as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients’ access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as “postamendments devices” because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360k) and part 807 (21 CFR part 807). FDA may also classify a device through ‘De Novo’ classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA shall classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients’ access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application (PMA) to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining “substantial equivalence”). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

For this device, FDA issued an order on June 10, 2009, finding the ViruLite Cold Sore Machine not substantially equivalent to a predicate not subject to PMA. Thus, the device remained in class III in accordance with section 513(f)(1) of the FD&C Act when we issued the order.

On June 30, 2009, Pacer Therapeutics, Ltd., submitted a request for De Novo classification of the ViruLite Cold Sore Machine. FDA reviewed the request in

52968 Federal Register / Vol. 83, No. 203 / Friday, October 19, 2018 / Rules and Regulations
order to classify the device under the
criteria for classification set forth in
section 513(a)(1) of the FD&C Act.

We classify devices into class II if
general controls by themselves are
insufficient to provide reasonable
assurance of safety and effectiveness,
but there is sufficient information to
establish special controls that, in
combination with the general controls,
provide reasonable assurance of the
safety and effectiveness of the device for
its intended use (see 21 U.S.C.
360c(a)(1)(B)). After review of the
information submitted in the request,
we determined that the device can be
classified into class II with the
establishment of special controls. FDA
has determined that these special
controls, in addition to the general
controls, will provide reasonable
assurance of the safety and effectiveness
of the device.

Therefore, on October 18, 2012, FDA
issued an order to the requester
classifying the device into class II. FDA
is codifying the classification of the
device by adding 21 CFR 878.4860. We
have named the generic type of device
light based energy source device for
topical application, and it is identified
as a device that emits light energy at
near infrared spectrum and is applied
externally to the surface of herpes
simplex labialis lesions on or around
the lips.

FDA has identified the following risks
to health associated specifically with
this type of device and the measures
required to mitigate these risks in table
1.

<table>
<thead>
<tr>
<th>Identified risks</th>
<th>Mitigation measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Redness and discomfort</td>
<td>Clinical performance testing, Usability testing, and Labeling.</td>
</tr>
<tr>
<td>Burns and blister</td>
<td>Clinical performance testing, Usability testing, and Labeling.</td>
</tr>
<tr>
<td>Adverse tissue reaction</td>
<td>Biocompatibility evaluation.</td>
</tr>
<tr>
<td>Infection/transmissibility</td>
<td>Labeling and disinfection validation, and Usability testing.</td>
</tr>
<tr>
<td>Electrical shock</td>
<td>Electrical safety testing and Labeling.</td>
</tr>
<tr>
<td>Electromagnetic incompatibility</td>
<td>Electromagnetic compatibility testing and Labeling.</td>
</tr>
<tr>
<td>User error</td>
<td>Usability testing and Labeling.</td>
</tr>
<tr>
<td>Ocular injury</td>
<td>Labeling and Non-clinical performance testing for ocular safety.</td>
</tr>
</tbody>
</table>

FDA has determined that special
controls, in combination with the
general controls, address these risks to
health and provide reasonable assurance
of safety and effectiveness. For a device
to fall within this classification, and
thus avoid automatic classification in
class III, it would have to comply with
the special controls named in this final
order. The necessary special controls
appear in the regulation codified by this
order. This device is subject to
premarket notification requirements
under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

We have determined under 21 CFR
25.34(b) that this action is of a type that
does not individually or cumulatively
have a significant effect on the human
environment. Therefore, neither an
environmental assessment nor an
environmental impact statement is
required.

IV. Paperwork Reduction Act of 1995

This final order establishes special
controls that refer to previously
approved collections of information
found in other FDA regulations and
guidance. These collections of
information are subject to review by the
Office of Management and Budget
(OMB) under the Paperwork Reduction
collections of information in the
guidance document "De Novo
Classification Process (Evaluation of
Automatic Class III Designation)" have
been approved under OMB control
number 0910–0844; the collections of
information in 21 CFR part 814, subparts
A through E, regarding premarket approval, have been
approved under OMB control number
0910–0231; the collections of
information in 21 CFR part 820, regarding quality system regulation,
have been approved under OMB control
number 0910–0073; the collections of
information in part 807, subpart E,
regarding premarket notification submissions, have been approved under OMB control
number 0910–0120; and the
collections of information in 21 CFR
part 801, regarding labeling, have been
approved under OMB control number
0910–0485.

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food,
Drug, and Cosmetic Act and under
authority delegated to the Commissioner
of Food and Drugs, 21 CFR part 878 is
amended as follows:

PART 878—GENERAL AND PLASTIC
SURGERY DEVICES

§ 878.4860 Light based energy source
device for topical application.

(a) Identification. The device emits
light energy at near infrared spectrum
and is applied externally to the surface
of herpes simplex labialis lesions on or
around the lips.

(b) Classification. Class II (special
controls). The special controls for this
device are:

(1) The technical parameters of the
device, including wavelength, treatment
time, treatment area, energy density,
spat size, and power, must be
characterized.

(2) The cleaning and disinfection
instructions for the device must be
validated.

(3) The device must be demonstrated
to be biocompatible.

(4) Performance testing must validate
electromagnetic compatibility (EMC),
ocular safety, and electrical safety of the
device.

(5) Labeling must direct end-users to
contact the device manufacturer and
MedWatch if they experience any
adverse events when using this device.

(6) Labeling must include specific
information pertinent to use of the
device by the intended patient
population and the treatment regimen.

(7) Simulated use testing must
include information from a usability,
label comprehension and self-selection
study to demonstrate that the device can
be used by the intended patient
population without any assistance.

(8) Clinical data must show adequate
reduction in time to healing and assess
risks of redness, discomfort, burns, and
blisters.
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Part 878
[Docket No. FDA–2018–N–3595]

Medical Devices; General and Plastic Surgery Devices; Classification of the Hemostatic Device for Intraluminal Gastrointestinal Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the hemostatic device for intraluminal gastrointestinal use into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the hemostatic device for intraluminal gastrointestinal use’s classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients’ access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective October 19, 2018. The classification was applicable on May 7, 2018.

FOR FURTHER INFORMATION CONTACT: Maegen Colehour, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G423, Silver Spring, MD, 20993–0002, 301–796–6436, Maegen.Colehour@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the hemostatic device for intraluminal gastrointestinal use as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients’ access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)(A)). We refer to these devices as “postamendments devices” because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(i)) and part 807 (21 CFR part 807). FDA may also classify a device through “De Novo” classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification, that is, 21 CFR part 807 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device and requiring premarket notification under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act. Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients’ access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(ii)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining “substantial equivalence”). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On March 9, 2017, Wilson-Cook Medical, Inc. submitted a request for De Novo classification of the Hemospray® Endoscopic Hemostat. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on May 7, 2018, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 878.4456. We have named the generic type of device hemostatic device for intraluminal gastrointestinal use, and it is identified as a prescription device that is endoscopically applied to the upper and/or lower gastrointestinal tract and is intended to produce hemostasis via absorption of fluid or other means.

FDA has identified the following risks to health associated specifically with this type of device and the measures