(b) Related Information


(i) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.


(ii) Reserved.

(3) For BRP-Powertrain GmbH & CO KG service information identified in this AD, contact BRP-Powertrain GmbH & Co. KG, Welser Strasse 32, A–4623 Gunskirchen, Austria; phone: +43 7246 601 9130; internet: www.rotax-aircraft-engine.com.

(4) You may view this service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148. In addition, you can access this service information on the Internet at http://www.regulations.gov by searching for and locating Docket No. FAA–2016–4878.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to http://www.archives.gov/federal-register/cfr/ibr-locations.html.

Issued in Kansas City, Missouri, on June 6, 2016.

Pat Mullen,
Acting Manager, Small Airplane Directorate, Aircraft Certification Service.
is codifying the classification of the device by adding 21 CFR 886.5838.

The device is assigned the generic name nasolacrimal compression device, and it is identified as a prescription device that is fitted to apply mechanical pressure to the nasal aspect of the orbital rim to reduce outflow through the nasolacrimal ducts.

The risks to health that may be associated with use of the nasolacrimal compression device are improper fit of the device (extended or aggressive use of this device may cause sequelae such as bruising and/or soreness) and improper use of the device (for the uncoordinated, a corneal abrasion may occur inadvertently). General controls of the FD&C Act, including compliance with the labeling requirements in 21 CFR part 801 and the Quality System Regulation (21 CFR part 820), are sufficient to mitigate these risks and reasonably assure safety and effectiveness. FDA believes that the general controls provide reasonable assurance of safety and effectiveness.

This nasolacrimal compression device is not safe for use except under the supervision of a practitioner licensed by law to direct the use of the device. As such, the device is a prescription device and must satisfy prescription labeling requirements (see 21 CFR 801.108, Prescription devices).

Section 510(k) of the FD&C Act provides that a class I device is not subject to the premarket notification requirements under section 510(k) of the FD&C Act, unless the device is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury. FDA has determined that the device does meet these criteria and, therefore, premarket notification is not required for the device. Thus, persons who intend to market this device need not submit a premarket notification containing information on the nasolacrimal compression device they intend to market prior to marketing the device, subject to the limitations on exemptions in 21 CFR 886.9.

II. Analysis of Environmental Impact

The Agency has 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.

III. Paperwork Reduction Act of 1995

This final order refers to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding the quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0483.

IV. Reference

The following reference is on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at http://www.regulations.gov.