

for that affected control surface, unless the FAA-approved repair instructions specify otherwise.

(6) Replacement of the affected part on an airplane with a part listed in table 1 of PAI SB No. 80–0455, constitutes terminating action for the repetitive inspections required by this AD for that part.

(7) You may incorporate the actions of PAI SB No. 80–0455, into your FAA-approved airplane inspection program (AIP) or maintenance program (instructions for continued airworthiness) to ensure the continuing airworthiness of each operated airplane.

(8) After November 16, 2017 (the effective date of this AD), you may install on an airplane an affected control surface not listed in table 1 of PAI SB No. 80–0455, provided that before further flight after installation, the affected control surface has been inspected as specified in this AD and found airworthy.

#### (g) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Mike Kiesov, Aerospace Engineer, FAA, Small Airplane Standards Branch, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4144; fax: (816) 329–4090; email: [mike.kiesov@faa.gov](mailto:mike.kiesov@faa.gov).

Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Contacting the Manufacturer*: For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, Small Airplane Standards Branch, FAA; or the European Aviation Safety Agency (EASA).

(3) *Reporting Requirements*: For any reporting requirement in this AD, a federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES–200.

#### (h) Related Information

Refer to MCAI European Aviation Safety Agency (EASA) AD No.: 2017–0045, dated

March 9, 2017 for related information. You may examine the MCAI on the Internet at <https://www.regulations.gov/document?D=FAA-2017-0648-0002>.

#### (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 this AD specifies otherwise.

(i) PIAGGIO AERO INDUSTRIES S.p.A. Mandatory Service Bulletin (SB) No.: 80–0455, dated January 13, 2017.

(ii) Reserved.

(3) For PIAGGIO AERO INDUSTRIES S.p.A. service information identified in this AD, contact PIAGGIO AERO INDUSTRIES S.p.A.—Continued Airworthiness, Via Pionieri e Aviatori d'Italia snc—16154 Genova, Italy; Telephone: +39 010 0998046; Fax: None; email: [airworthiness@piaggioaerospace.it](mailto:airworthiness@piaggioaerospace.it); Internet: [www.piaggioaerospace.it/en/customer-support#care](http://www.piaggioaerospace.it/en/customer-support#care).

(4) You may view this service information at the FAA, Policy and Innovation Division, 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–2017–0648.

(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 September 29, 2017.

**Pat Mullen,**

*Acting Deputy Director, Policy & Innovation Division, Aircraft Certification Service.*

[FR Doc. 2017–21443 Filed 10–11–17; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 882

[Docket No. FDA–2017–N–1608]

#### Medical Devices; Neurological Devices; Classification of Cranial Motion Measurement Device; Correction

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final order; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a

final order entitled “Medical Devices; Neurological Devices; Classification of Cranial Motion Measurement Device” that appeared in the **Federal Register** of July 28, 2017. The final order was published with an incorrect statement in the preamble about whether FDA planned to exempt the device from premarket notification requirements. This document corrects that error.

**DATES:** Effective October 12, 2017.

**FOR FURTHER INFORMATION CONTACT:** Jay Gupta, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2611, Silver Spring, MD 20993–0002, 301–796–2795, [jay.gupta@fda.hhs.gov](mailto:jay.gupta@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of July 28, 2017 (82 FR 35069), FDA published the final order “Medical Devices; Neurological Devices; Classification of Cranial Motion Measurement Device.” The final order published with an incorrect statement in the preamble about whether FDA planned to exempt the device from premarket notification requirements under section 510(k) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360(k)).

#### Correction

In the **Federal Register** of July 28, 2017, in FR Doc. 2017–15895, the following correction is made:

On page 35070, after table 1 in the third column, the last paragraph is corrected to read as follows:

“Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k), if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the cranial motion measurement device they intend to market.”

Dated: October 4, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017–21982 Filed 10–11–17; 8:45 am]

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