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 Renton, Washington, on September 9, 2015.

Michael Kaszycki,
Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–23539 Filed 9–21–15; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39


RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are superseding Airworthiness Directive (AD) 2011–19–04, for all Airbus Model A318, A319, A320, and A321 series airplanes. AD 2011–19–04 required repetitive inspections for cracking of the left-hand and right-hand inboard and outboard elevator servo-control rod eye-ends, and corrective actions if necessary. This new AD requires an inspection to determine if certain elevator servo-control parts are installed and may have the potential of cracking, and replacement if necessary. This AD was prompted by a determination that certain elevator servo-control parts that do not conform to the approved type design have been installed and may have the potential of cracks in the rod eye-end. We are issuing this AD to detect and correct rod eye-end cracking, which could result in uncontrolled elevator surface and consequent reduced control of the airplane.

DATES: This AD becomes effective October 27, 2015.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of October 27, 2015.

The Director of the Federal Register approved the incorporation by reference of a certain other publication listed in this AD as of September 22, 2009 (74 FR 41611 August 18, 2009).


For Airbus service information identified in this AD, contact Airbus, Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email account.airworth-eas@airbus.com; Internet http://www.airbus.com. For UTC service information identified in this AD, contact UTC Aerospace Systems; Roger Dangremont; telephone +01 34 32 63 28; email roger.dangremont@goodrich.com. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at http://www.regulations.gov by searching for and locating Docket No. FAA–2014–0753.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2011–19–04, Amendment 39–16809 (76 FR 57630, September 16, 2011). AD 2011–19–04 applied to all Model A318, A319, A320, and A321 series airplanes. The NPRM published in the Federal Register on October 21, 2014 (79 FR 62928). The NPRM was prompted by a determination that certain elevator servo-control parts that do not conform to the approved type design have been installed and may have the potential of cracks in the rod eye-end. The NPRM proposed to continue to require repetitive inspections of the left-hand and right-hand inboard and outboard elevator servo-control rod eye-ends for cracking, and corrective actions if necessary. The NPRM also proposed to require an inspection to determine if certain elevator servo-control parts are installed, and replacement if necessary. We are issuing this AD to detect and correct rod eye-end cracking, which could result in uncontrolled elevator surface and consequent reduced control of the airplane.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2014–0137, dated May 28, 2014 (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition. The MCAI states:

One case of elevator servo-control disconnection was reported on an A320 family aeroplane. Investigation results revealed that the failure occurred at the servo-control rod eye-end. Prompted by this finding, additional inspections revealed cracking at the same location on a number of other servo-control rod eye-ends. In several cases, both actuators of the same elevator surface were affected.

It was determined that the detected rod end cracks are caused by fatigue, induced by a bending effect which is linked to the spherical bearing rotational torque. As the elevator surface is neither actuated nor damped, a dual servo-control disconnection on the same elevator would result in an uncontrolled surface.

This condition, if not corrected, could result in reduced control of the aeroplane.

To address this potential unsafe condition, EASA issued [an airworthiness directive (later revised)] [which corresponds to FAA AD 2009–17–04, Amendment 39–15995 (74 FR 41611, August 18, 2009)] to require a one-time inspection of the elevator servo-control rod eye-ends for aeroplanes which had accumulated more than 10,000 flight cycles (FC) since aeroplane first flight and, in case of findings, accomplishment of corrective actions.

As a result of EASA AD 2008–0149, a significant number of rod eye-ends were found cracked. In addition, some cracks were reported on rod eye-ends that had not yet accumulated the 10,000 FC of the established threshold.

Prompted by these findings, EASA issued [an airworthiness directive (later revised)] [which corresponds to FAA AD 2011–19–04, Amendment 39–16809 (76 FR 57630, September 16, 2011)], which partially retained the initial inspection requirement of EASA AD 2008–0149, which was superseded, reduced the compliance time of the initial inspection and introduced a repetitive inspection programme.

After EASA AD 2010–0046R1 (http://ad.easa.europa.eu/blob/ad_easa_ad_2010_0046_R1_superseded.pdf) AD 2010–0046R1 was issued, a new elevator servo-control rod eye-end was developed, incorporating a re-greasable roller bearing.

Consequently, EASA issued [EASA AD 2013–0309 (later corrected) (http://ad.easa.europa.eu/ blob/ad_easa_ad_2013_0309_superseded.pdf) AD 2013–0309], retaining the requirements of EASA AD 2010–0046R1, which was superseded, and introduced an
optional terminating action for the repetitive inspections by replacing the existing elevator servo-control rod eye-ends with the new elevator servo-control rod eye-end. In addition, that [EASA] AD prohibited, for aeroplanes that incorporate this optional modification, (re)installation of unmodified elevator servo-controls.

At the time that EASA AD 2013–0309 was issued, it was planned that Airbus would proceed with the certification of certain elevator servo-controls, Part Number (P/N) 31075–0xx, P/N 31075–1xx and P/N 31075–3xx (originally certified only for installation on Model A320–111 aeroplanes, which are no longer in service), to allow installation of those parts on other A320 family aeroplane Models.

Since that [EASA] AD was issued, Airbus decided not to progress with certification of the affected elevator servo-controls for installation on other Models.

For the reason described above, and because of evidence that such parts remain available as spares in the field, this [EASA] AD retains the requirements of EASA AD 2013–0309, which is superseded, and adds a prohibition to install the affected elevator servo-controls that were only intended for A320–111 aeroplanes.

This AD requires an inspection to determine whether any elevator control part having P/N 31075–0xx, 31075–1xx, or 31075–3xx is installed, and replacement if necessary. You may examine the MCAI in the AD docket on the Internet at http://www.regulations.gov/#/documentDetail?D=FAA-2014-0753-0002.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the NPRM (79 FR 62928, October 21, 2014) and the FAA’s response to each comment.

Request To Clarify Affected Airplanes for Certain Proposed Requirements

United Airlines (UAL) requested that, for clarity reasons, we revise the identity of affected airplanes in paragraphs (g) through (j) of the proposed AD (79 FR 62928, October 21, 2014) to pertain only to elevator servo-controls having part number (P/N) 341203 or P/N 341203–xxx rod eye-ends. UAL stated that per Airbus Service Bulletin A320–27A1186, Revision 07, dated March 2, 2011; and Goodrich Service Bulletin 31075–27–22, dated July 2, 2013, it understands that only the rod eye-ends fitted with self-lubricating spherical bearings are required to have initial and repetitive inspections for cracks.

We partially agree with the commenter’s request. We agree that only certain elevator servo-controls and rod eye-ends are affected. However, paragraph (n) of this AD addresses the commenter’s concern. Paragraph (n) of this AD identifies airplanes that are not affected by the requirements of paragraphs (g), (h), (k) and (l) of this AD. We have not changed this AD as requested by the commenter, but we have revised the heading of paragraph (n) of this AD to more accurately reflect the content of that paragraph.

Request To Permit the Use of Serviceable Parts, and Relocate the Definition of Serviceable Parts

UAL requested that we permit the use of serviceable parts in paragraph (l)(1) of the proposed AD (79 FR 62928, October 21, 2014), and move the definition of a serviceable part from paragraph (l)(2) of the proposed AD to paragraph (l)(1) of the proposed AD.

We agree with the commenter’s requests. We have determined that the use of serviceable parts is acceptable as replacement parts in paragraph (l)(1) of this AD. We have changed the wording of paragraph (l)(1) of this AD to specify that serviceable parts may be used as replacement parts. We have also moved the definition of serviceable parts from paragraph (l)(2) of this AD to paragraph (l)(1) of this AD since both paragraphs (l)(1) and (l)(2) of this AD specify the use of serviceable parts.

Request To Revise Service Information Title


We agree with the commenter’s request. The requested service bulletin title change is correct. We have revised paragraph (l)(2) of this AD accordingly.

Conclusion

We reviewed the available data, including the comments received, and determined that air safety and the public interest require adopting this AD with the changes described previously and minor editorial changes. We have determined that these changes:

• Are consistent with the intent that was proposed in the NPRM (79 FR 62928, October 21, 2014) for correcting the unsafe condition; and
• Do not add any additional burden upon the public than was already proposed in the NPRM (79 FR 62928, October 21, 2014).

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this AD.

Related Service Information Under 1 CFR Part 51

Airbus has issued Service Bulletin A320–27–1223, dated September 3, 2013; and UTC Aerospace Systems Service Bulletin 31075–27–22, dated July 2, 2013. The service information describes procedures for modifying and replacing the elevator servo-control eye-end. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section of this AD.

Costs of Compliance

We estimate that this AD affects 851 airplanes of U.S. registry.

The actions that are required by AD 2011–19–04, Amendment 39–16809 (76 FR 57630, September 16, 2011), and retained in this AD take about 25 work-hours per product, at an average labor rate of $85 per work-hour. Based on these figures, the estimated cost of the actions that are required by AD 2011–19–04 is $2,125 per product.

We also estimate that it would take about 14 work-hours per product to comply with the basic requirements of this AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of this AD on U.S. operators to be $1,012,690, or $1,190 per product.

In addition, we estimate that any necessary follow-on actions would take about 2 work-hours and require parts costing $4,000, for a cost of $4,170 per product. We have no way of determining the number of aircraft that might need this action.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA’s authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. “Subtitle VII: Aviation Programs,” describes in more detail the scope of the Agency’s authority.

We are issuing this rulemaking under the authority described in “Subtitle VII, Part A, Subpart III, Section 44701: General requirements.” Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on
products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

1. Is not a “significant regulatory action” under Executive Order 12866;
2. Is not a “significant rule” under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Examining the AD Docket

You may examine the AD docket on the Internet at http://www.regulations.gov/#docketDetail;D=FAA-2014-0753; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the ADDRESSES section.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

§ 39.13 [Amended]

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2011–19–04, Amendment 39–16809 (76 FR 57630, September 16, 2011), and adding the following new AD:


(a) Effective Date

This AD becomes effective October 27, 2015.

(b) Affected ADs


(c) Applicability

This AD applies to the airplanes identified in paragraphs (c)(1) through (c)(4) of this AD, certified in the category, all manufacturer serial numbers.


(d) Subject

Air Transport Association (ATA) of America Code 27, Flight Controls.

(e) Reason

This AD was prompted by a determination that certain elevator servo-control parts that do not conform to the approved type design have been installed and may have the potential of cracks in the rod eye-end. We are issuing this AD to detect and correct rod eye-end cracking, which could result in uncontrolled elevator surface and consequent reduced control of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Retained Inspections

This paragraph restates the requirements of paragraph (g) of AD 2011–19–04, Amendment 39–16809 (76 FR 57630, September 16, 2011), without changes.


2. For airplanes that have accumulated 10,000 total flight cycles or more as of September 22, 2009 (the effective date of AD 2009–17–04, Amendment 39–15995 (74 FR 41611, August 18, 2009)): At the later of the times specified in paragraphs (g)(2)(i) and (g)(2)(ii) of this AD: Inspect both the left-hand and right-hand outboard elevator servo-control rod eye-ends for cracking, in accordance with the instructions of Airbus AOT A320–27A1186, Revision 04, dated April 3, 2009, or the Accomplishment Instructions of Airbus Service Bulletin A320–27A1186, Revision 07, dated March 2, 2011. As of October 21, 2011 (the effective date of AD 2011–19–04, Amendment 39–16809 (76 FR 57630, September 16, 2011)), use Airbus Service Bulletin A320–27A1186, Revision 07, dated March 2, 2011.

3. For airplanes that have accumulated less than 10,000 total flight cycles as of September 22, 2009 (the effective date of AD 2009–17–04, Amendment 39–15995 (74 FR 41611, August 18, 2009)): At the later of the times specified in paragraphs (g)(2)(i)(A) and (g)(2)(i)(B) of this AD. The inspections thereafter at intervals not to exceed 5,000 flight cycles.

4. For airplanes that have accumulated less than 10,000 total flight cycles as of September 22, 2009 (the effective date of AD 2009–17–04, Amendment 39–15995 (74 FR 41611, August 18, 2009)):
   (A) Before the accumulation of 7,500 total flight cycles.
   (B) Within 40 months after October 21, 2011 (the effective date of AD 2011–19–04, Amendment 39–16809 (76 FR 57630, September 16, 2011)) but no later than before the accumulation of 13,000 total flight cycles.

(h) Retained Repetitive Inspections

This paragraph restates the requirements of paragraph (h) of AD 2011–19–04, Amendment 39–16809 (76 FR 57630, September 16, 2011), with no changes. Repeat the inspections of the left-hand and right-hand inboard and outboard elevator servo-control rod eye-ends for cracking as required by paragraphs (g)(1) and (g)(2) of this AD at the later of the times specified in paragraph (h)(1) or (h)(2) of this AD. Repeat the inspections thereafter at intervals not to exceed 5,000 flight cycles.
Airbus Service Bulletin A320–27A1186, with the Accomplishment Instructions of without any crack findings, in accordance inspected for cracks in the rod eye-ends Serviceable parts are those that have been EASA Design Organization Approval (DOA). Avocation Safety Agency (EASA); or Airbus’s Airplane Directorate, FAA; or the European 31075–3xx with serviceable parts having P/ (l)(1) or (l)(2) of this AD. (m) New Optional Terminating Action for Certain Inspections Modification of an airplane by replacing all 4 elevator servo-control rod eye-ends with modified (i.e. re-greasable) parts, and re-identification of those elevator servo-controls to P/N 31075–6xx or P/N 31075–8xx, as applicable, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–27–2223, dated September 3, 2013; or UTC Aerospace Systems Service Bulletin 31075– 27–22, dated July 2, 2013, (n) Airplanes Excluded From Certain Inspection Requirements Airplanes on which Airbus Modification 154554 (installation of servo-controls having P/N 31075–6xx o P/N 31075–8xx, fitted with modified rod eye-end roller bearing) has been embodied in production are not affected by the requirements of paragraphs (g), (h), (k), and (l) of this AD, provided that no elevator servo-control having P/N 31075–6xx, or P/N 31075–8xx, fitted with rod eye- end assembly P/N 314203-xxx, has been reinstalled since first flight. (o) Credit for Previous Actions (1) This paragraph restates the credit specified in paragraph (k) of AD 2011–19–04, Amendment 39–16809 (76 FR 57630, September 16, 2011). (2) Replace all elevator servo-controls having P/N 31075–0xx, 31075–1xx, or 31075–3xx with serviceable parts having P/N 31075–6xx or 31075–8xx, as applicable, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–27–22, dated March 2, 2011. (2) Within 6 months after October 21, 2011 (the effective date of AD 2011–19–04, Amendment 39–16809 (76 FR 57630, September 16, 2011)). (i) Retained Corrective Actions This paragraph restates the requirements of paragraph (i) of AD 2011–19–04, Amendment 39–16809 (76 FR 57630, September 16, 2011), with no changes. As of October 21, 2011 (the effective date of AD 2011–19–04, Amendment 39–16809 (76 FR 57630, September 16, 2011)), and except as required by paragraph (p) of this AD, no person may install on any airplane an elevator servo-control rod eye-end unless it is new or has been inspected in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–27A11186, Revision 07, dated March 2, 2011. (j) Retained Parts Installation Limitation for Elevator Servo-Control Rod Eye-Ends This paragraph restates the requirements of paragraph (j) of AD 2011–19–04, Amendment 39–16809 (76 FR 57630, September 16, 2011), with a new exception. As of October 21, 2011, the new exception. As of October 21, 2011 (the effective date of AD 2011–19–04, Amendment 39–16809 (76 FR 57630, September 16, 2011)), and except as required by paragraph (p) of this AD, no person may install on any airplane an elevator servo-control rod eye-end unless it is new or has been inspected in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–27A11186, Revision 07, dated March 2, 2011, with no crack findings. (k) New Requirement of This AD: Inspection To Determine Part Numbers As of the effective date of this AD: At the later of the times specified in paragraphs (k)(1) and (k)(2) of this AD, do an inspection to determine whether any elevator control part having part number P/N 31075–6xx, 31075–1xx, or 31075–3xx is installed. A review of airplane maintenance records is acceptable in lieu of this inspection if the part numbers of the elevator control parts can be conclusively determined from that review. (1) Concurrently with the accomplishment of the next inspection required by paragraph (g) or (h) of this AD. (2) Within 30 days after the effective date of this AD. (1) This paragraph restates the credit specified in paragraph (k) of AD 2011–19–04, Amendment 39–16809 (76 FR 57630, September 16, 2011). (i) For airplanes that do not have Airbus Modification 154545 embodied in production: After optional modification of the airplane as specified in paragraph (m) of this AD. (ii) For airplanes on which Airbus Modification 154545 has been embodied in production: As of the effective date of this AD. (q) Other FAA AD Provisions The following provisions also apply to this AD: (1) Alternative Methods of Compliance (AMOCs): The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Sanjay Ralhan, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–1405; fax 425–227–1149. Information may be emailed to: 9-ANM-116-AMOC-REQUESTS@faa.gov. (i) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/ certificate holding district office. The AMOC approval letter must specifically reference this AD. (ii) AMOCs approved previously for AD 2011–19–04, Amendment 39–16809 (76 FR 57630, September 16, 2011), are approved as AMOCs for the corresponding provisions of this AD.
(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, International Branch, ANM–116, Transport Airplane Directorate, FAA; or EASA; or Airbus’s EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(c) Related Information


(2) Airbus Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (s)(6) and (s)(8) of this AD.

(s) 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.

(3) The following service information was approved for IBR on October 27, 2015.


(4) The following service information was approved for IBR on October 21, 2011 (76 FR 57630, September 16, 2011).

(i) Airbus Service Bulletin A320–27A1186, Revision 07, including Appendices 1, 2, 3, 4, 5, and 6, dated March 2, 2011.

(ii) Reserved.

(5) The following service information was approved for IBR on September 22, 2009 (74 FR 41611, August 18, 2009).


(ii) Reserved.

(iii) Airworthiness Office—EIAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email account.airworth-eas@airbus.com; Internet http://www.airbus.com.

(7) For UTC service information identified in this AD, contact UTC Aerospace Systems; Roger Dangremont; telephone +01 34 32 63 28; email roger.dangremont@goodrich.com.

(8) You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(9) 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 Renton, Washington, on September 11, 2015.

Michael Kaszyczyk,
Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–23541 Filed 9–21–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

21 CFR Part 886

[Docket No. FDA–2015–N–3044]

Medical Devices; Ophthalmic Devices; Classification of the Oral Electronic Vision Aid

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the oral electronic vision aid into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the oral electronic vision aid’s classification.

The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective September 22, 2015. The classification was applicable on June 18, 2015.

FOR FURTHER INFORMATION CONTACT: Dexiu Shi, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2246, Silver Spring, MD, 20903–0002, 301–796–6470, dexiu.shi@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postmarket devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(f), to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act (21 U.S.C. 360c(f)(2)), as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1), the person requests a reclassification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act.

If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of “low-moderate risk” or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device.

On August 7, 2013, Wicab Inc., submitted a request for classification of the BrainPort V100 under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1). In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1). FDA classifies