From	To	MEA	MAA
§ 95.7001 Jet Routes			
§ 95.7189 Jet Route No. 189 is Amended to Read in Part			
Klamath Falls, OR VORTAC	Battle Ground, WA VORTAC	#19000	45000
#MEA is established with a gap in navigation signal coverage			
§ 95.8003 VOR Federal Airway Changeover Points Airway Segment V–16 is Amended to Add Changeover Point			
From	To	Changeover points	
		Distance	From
Pulaski, VA VORTAC	Roanoke, VA VORTAC	10	Pulaski
V–603 is Amended to Add Changeover Point			
Elfee, AK NDB	Dillingham, AK VOR/DME	207	Elfee
V–617 is Amended to Add Changeover Point			
Homer, AK VORTAC	Johnstone Point, AK VORTAC	63	Homer
§ 95.8005 Jet Routes Changeover Points Airway Segment J–189 is Amended to Modify Changeover Point			
Klamath Falls, OR VORTAC	Battle Ground, WA VORTAC	78	Klamath Falls
#MEA is established with a gap in navigation signal covera			

[FR Doc. 00–933 Filed 1–13–00; 8:45 am]
BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 121, 125

[Docket No. FAA–1999–6140; Amendment Nos. 121–271 and 125–32]

RIN 2120–AG88

Revisions to Digital Flight Data Recorder Requirements for Airbus Airplanes; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final Rule; correction.

SUMMARY: The FAA published a final rule in the **Federal Register** on August 24, 1999, (64 FR 46117). The rule amended the flight data recorder regulations by adding language to allow certain Airbus airplanes to record certain data parameters using resolution and sampling requirements that differed slightly from the regulation. This document makes certain corrections to Appendix E to Part 125, Airplane Flight Recorder Specifications.

EFFECTIVE DATE: August 17, 1999.

FOR FURTHER INFORMATION CONTACT: Gary E. Davis, Air Carrier Operations Branch (AFS–201), Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591, telephone (202) 267–8166.

SUPPLEMENTARY INFORMATION: On August 24, 1999, the FAA published an amendment to the flight data recorder requirements of 14 CFR Parts 121 and 125 (64 FR 46117). In the amendment to Appendix E to Part 125, Airplane Flight Recorder Specifications, one parameter listing was inadvertently omitted. This action corrects that omission.

Correction

In FR Doc. 99–21783, published on August 24, 1999 (64 FR 46117), make the following correction:

On page 46122, third column, in Appendix E to Part 125, Airplane Flight Recorder Specifications, insert parameter 21, in numerical order, to read as follows:

* * * * *

Appendix E to Part 125—Airplane Flight Recorder Specifications

The recorded values must meet the designated range, resolution, and accuracy requirements during dynamic and static conditions. All data recorded must be correlated in time to within one second.

Parameters	Range	Accuracy (sensor input)	Seconds per sampling interval	Resolution	Remarks
* * *	*	*	*		*
21. Leading Edge Flap or Cockpit Control Selection [11].					
* * *	*	*	*		*

* * * * *

Issued in Washington, DC on January 12, 2000.

Donald P. Byrne,

Assistant Chief Counsel, Regulations Division.

[FR Doc. 00–1056 Filed 1–13–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 862, 864, 866, 868, 870, 872, 874, 876, 878, 880, 882, 884, 886, 888, 890, and 892

[Docket No. 98N–0009]

Medical Devices; Exemption From Premarket Notification and Reserved Devices; Class I

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its classification regulations to designate class I devices that are exempt from the premarket notification requirements, subject to certain limitations, and to designate those class I devices that remain subject to premarket notification requirements under the new statutory criteria for premarket notification requirements. The devices FDA is designating as exempt do not include class I devices that have been previously exempted by regulation from the premarket notification requirements. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (SMDA), and the FDA Modernization Act of 1997 (FDAMA). FDA is taking this action in order to implement a requirement of FDAMA. Elsewhere in this issue of the **Federal Register**, FDA is announcing that it is withdrawing proposed rules to revoke existing exemptions from premarket notification for two devices.

DATES: This regulation is effective February 14, 2000.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Under section 513 of the act (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the 1976 amendments (Public Law 94–295), as amended by the SMDA (Public Law 101–629), devices are to be classified into class I (general controls) if there is information showing that the general controls of the act are sufficient to ensure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device, or is for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices) are classified through the premarket notification process under section 510(k) of the act (21 U.S.C. 360(k)). Section 510(k) of the act and the implementing regulations, part 807 (21 CFR part 807), require persons who intend to market a new device to submit a premarket notification report (510(k)) containing information that allows FDA to determine whether the new device is substantially equivalent within the meaning of section 513(i) of the act to a legally marketed device that does not require premarket approval. Unless exempted from premarket notification requirements, persons may not market a new device under section 510(k) of the act, unless they receive a substantial equivalence order from FDA or an order reclassifying the device into class I or class II, under section 513(f) of the act.

On November 21, 1997, the President signed FDAMA into law (Public Law 105–115). Section 206 of FDAMA, in part, added a new section 510(l) to the act. Under section 206 of FDAMA, new section 510(l) of the act became effective on February 19, 1998. New section 510(l) of the act provides that a class I device is exempt from the premarket notification requirements under section 510(k) of the act, unless the device is intended for a use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury. This document refers to devices that FDA believes meet these criteria as ''reserved.'' FDA has evaluated all class I devices to determine which device types should be subject to premarket notification requirements.

In developing the list of reserved devices, the agency considered its experience in reviewing premarket notifications for these device types, focusing on the risk inherent with the device and/or the disease being treated or diagnosed. FDA believes that the devices listed as reserved are intended for a use that is of substantial importance in preventing impairment of human health or present a potential unreasonable risk of illness or injury.

II. Limitations on Exemptions

FDA believes that the generic types of class I devices listed herein, in addition to a vast majority of class I devices previously exempted, should be exempt from the premarket notification requirements under section 510(l) of the act. FDA further believes, however, that these generic device categories should be exempt only to the extent that they have existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices (IVD's), only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. FDA believes that certain changes to devices within a generic device type that is generally exempt may make the device intended for a use that is of substantial importance in preventing impairment of human health or may make the device present a potential unreasonable risk of illness or injury. Accordingly, devices changed in this manner would fall within the reserved criteria under section 510(l) of the act and would require premarket notification.

FDA believes that devices that have different intended uses than legally marketed devices in that generic device type present a potential unreasonable risk of illness or injury because their safety and effectiveness characteristics