

- Hallock, MN, Hallock Muni, RNAV (GPS) RWY 31, Orig
- Hallock, MN, Hallock Muni, Takeoff Minimums and Obstacle DP, Orig
- Little Falls, MN, Little Falls/Morrison County-Lindbergh Fld, GPS RWY 31, Orig-A, CANCELLED
- Little Falls, MN, Little Falls/Morrison County-Lindbergh Fld, RNAV (GPS) RWY 31, Orig
- Marshall, MN, Southwest Minnesota Rgnl/Marshall/Ryan Fld, GPS RWY 30, Orig-A, CANCELLED
- Marshall, MN, Southwest Minnesota Rgnl/Marshall/Ryan Fld, RNAV (GPS) RWY 30, Orig
- St Paul, MN, Lake Elmo, NDB RWY 4, Amdt 5
- St Paul, MN, Lake Elmo, RNAV (GPS) RWY 32, Amdt 1
- Moberly, MO, Omar N Bradley, VOR/DME RNAV OR GPS RWY 13, Amdt 1, CANCELLED
- Moberly, MO, Omar N Bradley, VOR/DME RNAV OR GPS RWY 31, Amdt 1, CANCELLED
- Clarksdale, MS, Fletcher Field, RNAV (GPS) RWY 18, Amdt 1
- Clarksdale, MS, Fletcher Field, RNAV (GPS) RWY 36, Amdt 1
- Tunica, MS, Tunica Muni, ILS or LOC/DME RWY 35, Amdt 1
- Tunica, MS, Tunica Muni, RNAV (GPS) RWY 17, Amdt 3
- Tunica, MS, Tunica Muni, RNAV (GPS) RWY 35, Amdt 2
- Tunica, MS, Tunica Muni, VOR/DME-A, Orig
- Bismarck, ND, Bismarck Muni, ILS OR LOC RWY 13, Amdt 3
- Bismarck, ND, Bismarck Muni, ILS OR LOC RWY 31, Amdt 33
- Bismarck, ND, Bismarck Muni, RNAV (GPS) RWY 3, Amdt 2
- Bismarck, ND, Bismarck Muni, RNAV (GPS) RWY 13, Orig
- Bismarck, ND, Bismarck Muni, RNAV (GPS) RWY 21, Amdt 1
- Bismarck, ND, Bismarck Muni, RNAV (GPS) RWY 31, Amdt 1
- Bismarck, ND, Bismarck Muni, VOR-A, Amdt 21
- Walhalla, ND, Walhalla Muni, Takeoff Minimums and Obstacle DP, Orig
- Creighton, NE, Creighton Muni, RNAV (GPS) RWY 13, Orig
- Creighton, NE, Creighton Muni, RNAV (GPS) RWY 31, Orig
- Creighton, NE, Creighton Muni, Takeoff Minimums and Obstacle DP, Orig
- Lincoln, NE, Lincoln, VOR RWY 17, Amdt 7
- Lincoln, NE, Lincoln, VOR RWY 18, Amdt 13
- Nashua, NH, Boire Field, RNAV (GPS) RWY 32, Orig-A
- Poughkeepsie, NY, Dutchess County, ILS OR LOC RWY 6, Amdt 6A
- Poughkeepsie, NY, Dutchess County, RNAV (GPS) RWY 6, Orig-A
- Poughkeepsie, NY, Dutchess County, VOR/DME RWY 6, Amdt 6A
- Watertown, NY, Watertown Intl, ILS OR LOC RWY 7, Amdt 7
- Watertown, NY, Watertown Intl, RNAV (GPS) RWY 7, Amdt 2
- Watertown, NY, Watertown Intl, VOR RWY 7, Amdt 14
- White Plains, NY, Westchester County, ILS OR LOC RWY 16, Amdt 23A
- Cadiz, OH, Harrison County, GPS RWY 13, Orig, CANCELLED
- Cadiz, OH, Harrison County, GPS RWY 31, Orig, CANCELLED
- Cadiz, OH, Harrison County, RNAV (GPS) RWY 13, Orig
- Cadiz, OH, Harrison County, RNAV (GPS) RWY 31, Orig
- Cadiz, OH, Harrison County, Takeoff Minimums and Obstacle DP, Amdt 3
- Cleveland, OH, Cleveland-Hopkins Intl, CONVERGING ILS RWY 24R, Amdt 1
- Cleveland, OH, Cleveland-Hopkins Intl, ILS OR LOC RWY 6R, ILS RWY 6R (SA CAT II), Amdt 21
- Cleveland, OH, Cleveland-Hopkins Intl, ILS OR LOC RWY 24L, ILS RWY 24L (SA CAT II), Amdt 22
- Cleveland, OH, Cleveland-Hopkins Intl, ILS OR LOC/DME RWY 24R, ILS RWY 24R (CAT II), ILS RWY 24R (CAT III), ILS RWY 24R (SA CAT I), Amdt 5
- Cleveland, OH, Cleveland-Hopkins Intl, ILS PRM RWY 24R (Simultaneous Close Parallel), Amdt 1
- Cleveland, OH, Cleveland-Hopkins Intl, RNAV (GPS) RWY 24L, Amdt 3
- Cleveland, OH, Cleveland-Hopkins Intl, RNAV (GPS) RWY 24R, Amdt 3
- Oklahoma City, OK, Wiley Post, ILS OR LOC RWY 35R, Orig
- Scappoose, OR, Scappoose Industrial Airpark, RNAV (GPS) RWY 15, Orig
- Scappoose, OR, Scappoose Industrial Airpark, VOR/DME-A, Amdt 3
- St. George, SC, St George, VOR/DME-A, Amdt 2, CANCELLED
- Dyersburg, TN, Dyersburg Rgnl, Takeoff Minimums and Obstacle DP, Amdt 1
- Gallatin, TN, Summer County Rgnl, Takeoff Minimums and Obstacle DP, Amdt 3
- Charlottesville, VA, Charlottesville-Albemarle, ILS OR LOC RWY 3, Amdt 14, CANCELLED
- Charlottesville, VA, Charlottesville-Albemarle, ILS OR LOC RWY 3, Orig
- Burlington, VT, Burlington Intl, RNAV (GPS) RWY 33, Orig, CANCELLED
- Burlington, VT, Burlington Intl, RNAV (GPS) Y RWY 33, Orig
- Burlington, VT, Burlington Intl, RNAV (GPS) Z RWY 33, Orig
- Amery, WI, Amery Muni, NDB RWY 18, Amdt 6A, CANCELLED
- Madison, WI, Dane County Rgnl-Traux Field, RNAV (GPS) RWY 14, Amdt 2
- Madison, WI, Dane County Rgnl-Traux Field, RNAV (GPS) RWY 32, Amdt 2
- Madison, WI, Dane County Rgnl-Traux Field, Takeoff Minimums and Obstacle DP, Amdt 8
- Madison, WI, Dane County Rgnl-Traux Field, VOR RWY 18, Amdt 1
- Madison, WI, Dane County Rgnl-Traux Field, VOR RWY 32, Amdt 1
- Middleton, WI, Middleton Muni-Morey Field, VOR RWY 10, Amdt 1
- Mosinee, WI, Central Wisconsin, ILS OR LOC RWY 8, Amdt 13
- Mosinee, WI, Central Wisconsin, ILS OR LOC RWY 35, Amdt 2
- Mosinee, WI, Central Wisconsin, RNAV (GPS) RWY 8, Amdt 1
- Mosinee, WI, Central Wisconsin, RNAV (GPS) RWY 17, Amdt 1
- Mosinee, WI, Central Wisconsin, RNAV (GPS) RWY 26, Amdt 1
- Mosinee, WI, Central Wisconsin, RNAV (GPS) RWY 35, Amdt 1
- Mosinee, WI, Central Wisconsin, VOR/DME RWY 35, Amdt 9
- Waupaca, WI, Waupaca Muni, RNAV (GPS) RWY 10, Amdt 1
- Waupaca, WI, Waupaca Muni, RNAV (GPS) RWY 28, Amdt 1
- On March 4, 2011 (76 FR 11944) the FAA published an Amendment in Docket No. 30770, Amdt 3414 to Part 97 of the Federal Aviation Regulations under section 97.33. The following entries, published in TL 11-07 effective for 05 MAY 2011, are hereby *rescinded*:
- Hartford, CT, Hartford-Brainard, LDA RWY 2, Amdt 1G
- Hartford, CT, Hartford-Brainard, VOR OR GPS-A, Amdt 9C
- On March 25, 2011 (76 FR 16690) the FAA published an Amendment in Docket No. 30772, Amdt 3416 to Part 97 of the Federal Aviation Regulations under section 97.33. The following entry, published in TL 11-08 effective for 05 MAY 2011, is hereby *rescinded*:
- Kamuela, HI, Waimea-Kohala, RNAV (GPS) RWY 4, Amdt 1
- On March 25, 2011 (76 FR 16691) the FAA published an Amendment in Docket No. 30772, Amdt 3416 to Part 97 of the Federal Aviation Regulations under section 97.33. The following entries, published in TL 11-08 effective for 05 MAY 2011, are hereby *rescinded*:
- Kamuela, HI, Waimea-Kohala, VOR/DME RWY 4, Amdt 1
- Niles, MI, Jerry Tyler Memorial, VOR OR GPS RWY 3, Amdt 7A, CANCELLED
- Niles, MI, Jerry Tyler Memorial, VOR OR GPS RWY 21, Amdt 3A, CANCELLED

[FR Doc. 2011-8934 Filed 4-14-11; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 97**

[Docket No. 30777; Amdt. No. 3421]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments**AGENCY:** Federal Aviation Administration (FAA), DOT.**ACTION:** Final rule.

SUMMARY: This rule establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes

occurring in the National Airspace System, such as the commissioning of new navigational facilities, adding new obstacles, or changing air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective April 15, 2011. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of April 15, 2011.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591;
2. The FAA Regional Office of the region in which the affected airport is located;
3. The National Flight Procedures Office, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or
4. 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/code_of_federal_regulations/ibr_locations.html.

Availability—All SIAPs are available online free of charge. Visit <http://nfdc.faa.gov> to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from:

1. FAA Public Inquiry Center (APA-200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or
2. The FAA Regional Office of the region in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT:

Harry J. Hodges, Flight Procedure Standards Branch (AFS-420) Flight Technologies and Programs Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082 Oklahoma City, OK 73125) telephone: (405) 954-4164.

SUPPLEMENTARY INFORMATION: This rule amends Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) by amending the referenced SIAPs. The complete regulatory description of each SIAP is listed on the appropriate FAA Form 8260, as modified by the National Flight Data Center (FDC)/Permanent Notice to Airmen (P-NOTAM), and is incorporated by reference in the amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 97.20 of Title 14 of the Code of Federal Regulations.

The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form documents is unnecessary. This amendment provides the affected CFR sections and specifies the types of SIAP and the corresponding effective dates. This amendment also identifies the airport and its location, the procedure and the amendment number.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP as amended in the transmittal. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained for each SIAP as modified by FDC/P-NOTAMs.

The SIAPs, as modified by FDC P-NOTAM, and contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these changes to SIAPs, the TERPS criteria were applied only to specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a FDC NOTAM as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for all these SIAP amendments requires making them effective in less than 30 days.

Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs are impracticable and contrary to the public interest and,

where applicable, that good cause exists for making these SIAPs effective in less than 30 days.

Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) Is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, and Navigation (Air).

Issued in Washington, DC, on April 1, 2011.

John M. Allen,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, Part 97, 14 CFR part 97, is amended by amending Standard Instrument Approach Procedures, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

- 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

- 2. Part 97 is amended to read as follows:

§§97.23, 97.25, 97.27, 97.29, 97.31, 97.33 and 97.35 [Amended]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

* * * *Effective Upon Publication*

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
5-May-11	NE	Lincoln	Lincoln	1/0794	3/23/11	ILS OR LOC RWY 18, Amdt 6F
5-May-11	FL	Venice	Venice Muni	1/1934	3/23/11	Takeoff Minimums and Obstacle DP, Amdt 2
5-May-11	NC	Greenville	Pitt-Greenville	1/2023	3/23/11	RNAV (GPS) RWY 2, Orig
5-May-11	NY	Niagara Falls	Niagara Falls Intl	1/2456	3/23/11	NDB OR GPS RWY 28R, Amdt 16A
5-May-11	NC	Greenville	Pitt-Greenville	1/2789	3/23/11	ILS OR LOC RWY 20, Amdt 4
5-May-11	TX	Dallas	Dallas Love Field	1/3002	3/23/11	RNAV (GPS) Z RWY 13L, Orig-B
5-May-11	VA	Orange	Orange County	1/5119	3/4/11	VOR/DME OR GPS A, Amdt 2A
5-May-11	GA	Rome	Richard B Russell	1/5120	3/4/11	ILS/DME RWY 1, Orig-A
5-May-11	NJ	Linden	Linden	1/5393	3/7/11	Takeoff Minimums and Obstacle DP, Amdt 2
5-May-11	NJ	Newark	Newark Liberty Intl	1/5735	3/4/11	RNAV (RNP) Z RWY 29, Orig-A
5-May-11	MD	Cambridge	Cambridge-Dorchester	1/6177	3/1/11	NDB OR GPS RWY 34, Amdt 7
5-May-11	FL	Deland	Deland Muni-Sidney H Taylor Field.	1/6474	3/1/11	RNAV (GPS) RWY 5, Orig
5-May-11	FL	Panama City	Northwest Florida Beaches Intl ..	1/6475	3/1/11	RNAV (GPS) RWY 16, Orig-B
5-May-11	FL	Panama City	Northwest Florida Beaches Intl ..	1/6476	3/1/11	RNAV (GPS) RWY 34, Orig-B
5-May-11	WV	Charleston	Yeager	1/6478	3/1/11	Takeoff Minimums and Obstacle DP, Amdt 8
5-May-11	RI	Providence	Theodore Francis Green State ..	1/6567	3/1/11	ILS RWY 34, Amdt 10B
5-May-11	NJ	Newark	Newark Liberty Intl	1/6957	3/4/11	RNAV (RNP) Y RWY 29, Orig-A
5-May-11	CT	Groton (New London)	Groton-New London	1/7378	3/7/11	ILS OR LOC RWY 5, Amdt 11B
5-May-11	VT	Morrisville	Morrisville-Stowe State	1/7381	3/9/11	NDB OR GPS B, Amdt 1C
5-May-11	VT	Morrisville	Morrisville-Stowe State	1/7382	3/9/11	Takeoff Minimums and Obstacle DP, Amdt 2
5-May-11	MS	Starkville	George M Bryan	1/7383	3/14/11	LOC/DME RWY 36, Orig
5-May-11	FL	Lakeland	Lakeland Linder Rgnl	1/7480	3/7/11	RNAV (GPS) RWY 27, Orig
5-May-11	NY	White Plains	Westchester County	1/7527	3/7/11	RNAV (RNP) Z RWY 34, Orig
5-May-11	MA	Falmouth	Cape Cod Coast Guard Air Station.	1/7535	3/7/11	ILS OR LOC RWY 32, Orig
5-May-11	KY	Lexington	Blue Grass	1/7821	3/1/11	ILS OR LOC RWY 22, Amdt 20
5-May-11	AL	Auburn	Auburn University Rgnl	1/7887	3/7/11	RNAV (GPS) RWY 18, Orig
5-May-11	AL	Auburn	Auburn University Rgnl	1/7888	3/7/11	RNAV (GPS) RWY 11, Orig
5-May-11	NY	Poughkeepsie	Dutchess County	1/8102	3/9/11	Takeoff Minimums and Obstacle DP, Amdt 1
5-May-11	TN	Memphis	Memphis Intl	1/8162	3/7/11	RNAV (RNP) Y RWY 18R, Orig
5-May-11	TN	Memphis	Memphis Intl	1/8163	3/7/11	RNAV (RNP) X RWY 18L, Orig
5-May-11	TN	Memphis	Memphis Intl	1/8164	3/7/11	RNAV (RNP) Y RWY 18L, Orig
5-May-11	PA	Perkasie	Pennridge	1/8350	3/7/11	Takeoff Minimums and Obstacle DP, Orig
5-May-11	DC	Washington	Washington Dulles Intl	1/8351	3/7/11	RNAV (GPS) RWY 12, Amdt 1
5-May-11	DC	Washington	Washington Dulles Intl	1/8353	3/7/11	RNAV (GPS) RWY 1L, Orig
5-May-11	WI	Madison	Blackhawk Airfield	1/8455	3/9/11	VOR OR GPS A, Orig-C
5-May-11	AL	Lanett	Lanett Muni	1/8471	3/7/11	VOR/DME OR GPS A, Amdt 2A
5-May-11	IA	Keokuk	Keokuk Muni	1/8893	3/9/11	RNAV (GPS) RWY 14, Orig
5-May-11	IA	Keokuk	Keokuk Muni	1/8894	3/9/11	ILS OR LOC/DME RWY 26, Orig
5-May-11	IA	Keokuk	Keokuk Muni	1/8895	3/9/11	RNAV (GPS) RWY 26, Orig
5-May-11	IA	Keokuk	Keokuk Muni	1/8896	3/9/11	RNAV (GPS) RWY 8, Orig
5-May-11	NC	Goldsboro	Goldsboro-Wayne Muni	1/9054	3/7/11	VOR A, Amdt 5
5-May-11	NC	Goldsboro	Goldsboro-Wayne Muni	1/9055	3/7/11	RNAV (GPS) RWY 23, Orig
5-May-11	NC	Goldsboro	Goldsboro-Wayne Muni	1/9056	3/7/11	ILS OR LOC RWY 23, Amdt 1A
5-May-11	NY	Middletown	Randall	1/9081	3/4/11	NDB RWY 26, Amdt 1
5-May-11	VA	Marion/Wytheville	Mouintain Empire	1/9082	3/4/11	RNAV (GPS) RWY 26, Orig
5-May-11	WV	Ravenswood	Jackson County	1/9088	3/4/11	Takeoff Minimums and Obstacle DP, Amdt 1
5-May-11	KS	Concordia	Blosser Muni	1/9097	3/9/11	GPS RWY 17, Orig-A
5-May-11	IL	Morris	Morris Muni-James R. Washburn.	1/9221	3/4/11	RNAV (GPS) RWY 18, Orig
5-May-11	VA	Martinsville	Blue Ridge	1/9234	3/4/11	LOC RWY 30, Amdt 1
5-May-11	NE	Lincoln	Lincoln	1/9352	3/23/11	ILS OR LOC RWY 36, Amdt 11E
5-May-11	IL	Peru	Illinois Valley Rgnl-Walter A Cuncan Field.	1/9358	3/9/11	LOC RWY 36, Amdt 3A
5-May-11	IL	Peru	Illinois Valley Rgnl-Walter A Cuncan Field.	1/9360	3/9/11	RNAV (GPS) RWY 18, Orig-A
5-May-11	IL	Peru	Illinois Valley Rgnl-Walter A Cuncan Field.	1/9362	3/9/11	RNAV (GPS) RWY 36, Orig-A
5-May-11	NY	New York	La Guardia	1/9829	3/9/11	RNAV (RNP) Z RWY 22, Orig
5-May-11	NY	Poughkeepsie	Dutchess County	1/9964	3/23/11	VOR A, Amdt 11
5-May-11	NY	Poughkeepsie	Dutchess County	1/9965	3/23/11	RNAV (GPS) RWY 24, Orig
5-May-11	NY	Poughkeepsie	Dutchess County	1/9966	3/23/11	VOR/DME RWY 24, Amdt 4A

[FR Doc. 2011-8930 Filed 4-14-11; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 884

[Docket No. FDA-2011-N-0118]

Medical Devices; Obstetrical and Gynecological Devices; Classification of the Hemorrhoid Prevention Pressure Wedge

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the hemorrhoid prevention pressure wedge into class II (special controls). The special controls will apply to the device in order to provide a reasonable assurance of safety and effectiveness of the device. A hemorrhoid prevention pressure wedge provides support to the perianal region during the labor and delivery process.

DATES: This rule is effective May 16, 2011. The classification was applicable on January 13, 2011.

FOR FURTHER INFORMATION CONTACT: Glenn Bell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. G112, Silver Spring, MD 20993-0002, 301-796-6531.

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 postamendments 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(i) of the FD&C Act (21 U.S.C. 360c(i)), 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 provides that any person who submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the FD&C Act. FDA will, within 60 days of receiving this request, classify the device by written order. This classification will be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing this classification.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on August 5, 2009, classifying the Hem-Avert Perianal Stabilizer into class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction

into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On August 17, 2009, Plexus Biomedical, Inc., submitted a petition requesting classification of the Hem-Avert Perianal Stabilizer 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 petition in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act. FDA classifies 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 provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls will provide reasonable assurance of the safety and effectiveness of the device.

The device is assigned the generic name hemorrhoid prevention pressure wedge, and it is identified as a hemorrhoid prevention pressure wedge that provides mechanical support to the perianal region during the labor and delivery process. External mechanical support of the perianal region is intended to help prevent the occurrence of external hemorrhoids associated with vaginal childbirth.

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

TABLE 1—HEALTH RISKS AND MITIGATIONS

Identified risk	Mitigation measures
Skin/tissue trauma (e.g., rectal and/or anal trauma, necrosis, thinning, abrasion, laceration to the perineum, vulvar hematoma, sloughing).	Nonclinical Analysis and Testing. Clinical Information. Labeling.
Device failure (e.g., material failure, slippage)	Nonclinical Analysis and Testing. Labeling.
Device failure—obstruction to the treatment area caused by inability to remove the instrument quickly	Device Description. Labeling.
Infection.	Labeling.
Adverse tissue reaction	Biocompatibility.
Pain	Nonclinical Analysis and Testing. Biocompatibility.

FDA believes that the following special controls address the risks to

health and provide reasonable assurance of the safety and effectiveness of the

device: (1) The sale, distribution, and use of this device are restricted to