effective date at least 30 days after publication is provided.

Further, the SIAPs and Takeoff Minimums and ODPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making some SIAPs effective in less than 30 days.

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.

Lists of Subjects in 14 CFR Part 97

Air traffic control, Airports, Incorporation by reference, Navigation (air).

Issued in Washington, DC, on November 26, 2021.

Thomas J. Nichols,

Aviation Safety, Flight Standards Service, Manager, Standards Section, Flight Procedures & Airspace Group, Flight Technologies & Procedures Division.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal Regulations, Part 97 (14 CRF part 97) is amended by establishing, amending, suspending, or removing Standard Instrument Approach Procedures and/or Takeoff Minimums and Obstacle Departure 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(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

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

Effective 30 December 2021

Boston, MA, KBOS, RNAV (RNP) X RWY 33L, Orig
Portsmouth, NH, KPSM, ILS OR LOC RWY 16, Amdt 3A
Portsmouth, NH, KPSM, RNAV (GPS) RWY 16, Amdt 3A
New York, NY, KLGA, ILS OR LOC RWY 4, Amdt 38
New York, NY, KLGA, RNAV (GPS) Y RWY 4, Amdt 4
New York, NY, KLGA, RNAV (RNP) Z RWY 4, Amdt 2

Effective 27 January 2022

Kodiak, AK, PADQ, ILS Y OR LOC Y RWY 26, Amdt 4
Headland, AL, KHDL, RNAV (GPS) RWY 9, Amdt 1B
Headland, AL, KHDL, RNAV (GPS) RWY 27, Amdt 1B
Orlando, FL, KMCO, RNAV (GPS) RWY 17L, Amdt 2B
Donalsonville, GA, Donalsonville Muni, Takeoff Minimums and Obstacle DP, Amdt 1
Spencer, IA, KSPW, RNAV (GPS) RWY 12, Amdt 1
Spencer, IA, KSPW, RNAV (GPS) RWY 30, Amdt 1C
Spencer, IA, KSPW, RNAV (GPS) RWY 36, Amdt 1B
Huntington, IN, KHHG, RNAV (GPS) RWY 10, Amdt 1
Huntington, IN, KHHG, RNAV (GPS) RWY 28, Amdt 1
Marshall, MI, KRMY, VOR/DME–A, Orig-B, CANCELLED
Jackson, MN, KMJQ, RNAV (GPS) RWY 13, Amdt 2
Moberly, MO, KMBY, RNAV (GPS) RWY 13, Amdt 1
Moberly, MO, KMBY, RNAV (GPS) RWY 31, Amdt 1
Moberly, MO, Omar N Bradley, Takeoff Minimums and Obstacle DP, Amdt 1
Grand Island, NE, KGRI, ILS OR LOC RWY 35, Amdt 10
Wurtsboro, NY, Wurtsboro-Sullivan County, Takeoff Minimums and Obstacle DP, Amdt 2A
Burnet, TX, KBMQ, RNAV (GPS) RWY 19, Orig-D

[FR Doc. 2021–27054 Filed 12–14–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31403; Amdt. No. 3986]

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 amends, suspends, or removes 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 for the 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 December 15, 2021. 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 December 15, 2021.

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

For Examination

1. U.S. Department of Transportation, Docket Ops–M30, 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590–0001;

2. The FAA Air Traffic Organization Service Area in which the affected airport is located;

3. The office of Aeronautical Information Services, 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, email *fr.inspection@nara.gov* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Availability

All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center online at *nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

FOR FURTHER INFORMATION CONTACT: Thomas J. Nichols, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., Registry Bldg. 29, Room 104, Oklahoma City, OK 73169. Telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This rule amends 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 (NFDC)/Permanent Notice to Airmen (P–NOTAM), and is incorporated by reference under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR 97.20. 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 on FAA form documents is unnecessary. This amendment provides the affected CFR sections, and specifies the SIAPs and Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure and the amendment number.

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPs, Takeoff Minimums and ODPs as identified in the amendatory language for part 97 of this final rule.

The Rule

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

The SIAPs and Takeoff Minimums and ODPs, as modified by FDC permanent NOTAM, and contained in this amendment are based on criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these changes to SIAPs and Takeoff Minimums and ODPs, 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 that created the need for these SIAP and Takeoff Minimums and ODP amendments require making them effective in less than 30 days.

Because of the close and immediate relationship between these SIAPs, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and, where applicable, under 5 U.S.C. 553(d), good cause exists for making these SIAPs effective in less than 30 days.

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, Navigation (Air).

Issued in Washington, DC, on November 26, 2021.

Thomas J. Nichols,

Aviation Safety, Flight Standards Service Manager, Standards Section, Flight Procedures & Airspace Group, Flight Technologies & Procedures Division.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Title 14, CFR part 97, (is amended by amending Standard Instrument Approach Procedures and Takeoff Minimums and ODPs, 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(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

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

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
30–Dec–21 ..	NH	Haverhill	Dean Meml	1/2641	9/3/21	This NOTAM, published in Docket No. 31401, Amdt No. 3984, TL 22–01, (86 FR 68541, December 3, 2021), is hereby rescinded in its entirety.

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
30–Dec–21 ..	IA	Hampton	Hampton Muni	1/6841	10/27/21	This NOTAM, published in Docket No. 31401, Amdt No. 3984, TL 22–01, (86 FR 68541, December 3, 2021), is hereby rescinded in its entirety.
30–Dec–21 ..	KS	Wichita	Colonel James Jabara	1/8670	8/16/21	This NOTAM, published in Docket No. 31401, Amdt No. 3984, TL 22–01, (86 FR 68541, December 3, 2021), is hereby rescinded in its entirety.
30–Dec–21 ..	IA	Hampton	Hampton Muni	1/0780	11/23/21	VOR/DME RWY 35, Amdt 1F.
30–Dec–21 ..	MI	Bellaire	Antrim County	1/0823	11/23/21	RNAV (GPS) RWY 2, Orig.
30–Dec–21 ..	SC	Columbia	Columbia Metro	1/1158	11/10/21	ILS OR LOC RWY 5, Amdt 1E.
30–Dec–21 ..	MO	Aurora	Jerry Sumners Sr Aurora Muni	1/1417	11/9/21	RNAV (GPS) RWY 18, Orig-B.
30–Dec–21 ..	MO	Aurora	Jerry Sumners Sr Aurora Muni	1/1419	11/9/21	RNAV (GPS) RWY 36, Orig-B.
30–Dec–21 ..	KS	Wichita	Wichita Dwight D Eisenhower Ntl.	1/1513	11/9/21	ILS OR LOC RWY 1L, Amdt 3C.
30–Dec–21 ..	MN	Worthington	Worthington Muni	1/2202	11/9/21	RNAV (GPS) RWY 18, Orig-B.
30–Dec–21 ..	MN	Worthington	Worthington Muni	1/2203	11/9/21	RNAV (GPS) RWY 11, Orig-A.
30–Dec–21 ..	MN	Worthington	Worthington Muni	1/2204	11/9/21	RNAV (GPS) RWY 29, Orig-A.
30–Dec–21 ..	MN	Worthington	Worthington Muni	1/2205	11/9/21	RNAV (GPS) RWY 36, Orig-A.
30–Dec–21 ..	MN	Worthington	Worthington Muni	1/2208	11/9/21	ILS OR LOC RWY 29, Amdt 1A.
30–Dec–21 ..	IA	Ottumwa	Ottumwa Rgnl	1/2220	11/9/21	ILS OR LOC RWY 31, Amdt 5E.
30–Dec–21 ..	IA	Ottumwa	Ottumwa Rgnl	1/2221	11/9/21	LOC/DME BC RWY 13, Amdt 3B.
30–Dec–21 ..	IA	Ottumwa	Ottumwa Rgnl	1/2222	11/9/21	RNAV (GPS) RWY 13, Orig-B.
30–Dec–21 ..	IA	Ottumwa	Ottumwa Rgnl	1/2223	11/9/21	RNAV (GPS) RWY 31, Orig.
30–Dec–21 ..	IA	Ottumwa	Ottumwa Rgnl	1/2224	11/9/21	VOR/DME RWY 13, Amdt 7B.
30–Dec–21 ..	TX	Jasper	Jasper County-Bell Fld	1/3206	11/9/21	RNAV (GPS) RWY 18, Orig.
30–Dec–21 ..	TX	Jasper	Jasper County-Bell Fld	1/3207	11/9/21	RNAV (GPS) RWY 36, Orig-B.
30–Dec–21 ..	MN	International Falls	Falls Intl-Einarson Fld	1/3225	11/10/21	VOR RWY 31, Amdt 15B.
30–Dec–21 ..	MN	International Falls	Falls Intl-Einarson Fld	1/3227	11/10/21	VOR RWY 13, Amdt 14A.
30–Dec–21 ..	MN	International Falls	Falls Intl-Einarson Fld	1/3231	11/10/21	RNAV (GPS) RWY 31, Orig-A.
30–Dec–21 ..	MN	International Falls	Falls Intl-Einarson Fld	1/3233	11/10/21	RNAV (GPS) RWY 13, Orig-A.
30–Dec–21 ..	NY	Batavia	Genesee County	1/3291	11/9/21	RNAV (GPS) RWY 10, Orig-B.
30–Dec–21 ..	IL	Salem	Salem-Leckrone	1/4314	11/10/21	RNAV (GPS) RWY 18, Amdt 1A.
30–Dec–21 ..	IL	Salem	Salem-Leckrone	1/4315	11/10/21	RNAV (GPS) RWY 36, Amdt 1A.
30–Dec–21 ..	TX	Houston	Houston Exec	1/4390	11/10/21	RNAV (GPS) RWY 18, Orig-A.
30–Dec–21 ..	TX	Houston	Houston Exec	1/4391	11/10/21	RNAV (GPS) RWY 36, Amdt 1.
30–Dec–21 ..	IL	Flora	Flora Muni	1/4418	11/12/21	RNAV (GPS) RWY 21, Amdt 2D.
30–Dec–21 ..	IL	Flora	Flora Muni	1/4420	11/12/21	RNAV (GPS) RWY 3, Amdt 2B.
30–Dec–21 ..	NC	Hickory	Hickory Rgnl	1/5283	11/10/21	RNAV (GPS) RWY 1, Amdt 1B.
30–Dec–21 ..	NY	Millbrook	Sky Acres	1/5336	11/10/21	VOR–A, Amdt 8.
30–Dec–21 ..	KS	Wichita	Wichita Dwight D Eisenhower Ntl.	1/5763	11/9/21	ILS OR LOC RWY 19R, Amdt 5G.
30–Dec–21 ..	KS	Wichita	Wichita Dwight D Eisenhower Ntl.	1/5764	11/9/21	ILS OR LOC RWY 1R, Amdt 17D.
30–Dec–21 ..	MA	Boston	General Edward Lawrence Logan Intl.	1/5872	11/10/21	RNAV (GPS) RWY 33L, Amdt 2C.
30–Dec–21 ..	OH	Shelby	Shelby Community	1/5921	11/12/21	VOR–A, Amdt 5A.
30–Dec–21 ..	WI	Kenosha	Kenosha Rgnl	1/6158	11/12/21	RNAV (GPS) RWY 15, Orig-B.
30–Dec–21 ..	WI	Kenosha	Kenosha Rgnl	1/6160	11/12/21	RNAV (GPS) RWY 33, Orig-B.
30–Dec–21 ..	MS	Hattiesburg	Hattiesburg Bobby L Chain Muni.	1/6996	11/15/21	RNAV (GPS) Y RWY 13, Amdt 2B.
30–Dec–21 ..	MS	Hattiesburg	Hattiesburg Bobby L Chain Muni.	1/6997	11/15/21	RNAV (GPS) Z RWY 13, Amdt 1B.
30–Dec–21 ..	FL	Jacksonville	Jacksonville Intl	1/7884	11/10/21	VOR/DME RWY 32, Amdt 2B.
30–Dec–21 ..	FL	Jacksonville	Jacksonville Intl	1/7887	11/10/21	RNAV (GPS) Z RWY 32, Amdt 2D.
30–Dec–21 ..	FL	Jacksonville	Jacksonville Intl	1/7889	11/10/21	RNAV (GPS) Z RWY 26, Amdt 2C.
30–Dec–21 ..	FL	Jacksonville	Jacksonville Intl	1/7891	11/10/21	RNAV (GPS) Z RWY 14, Amdt 2B.
30–Dec–21 ..	FL	Jacksonville	Jacksonville Intl	1/7894	11/10/21	RNAV (GPS) Z RWY 8, Amdt 2B.
30–Dec–21 ..	NY	Batavia	Genesee County	1/8401	11/9/21	VOR/DME–A, Amdt 5B.
30–Dec–21 ..	NY	Batavia	Genesee County	1/8417	11/9/21	ILS OR LOC RWY 28, Amdt 6B.
30–Dec–21 ..	NY	Batavia	Genesee County	1/9021	11/9/21	RNAV (GPS) RWY 28, Orig.
30–Dec–21 ..	SC	Columbia	Columbia Metro	1/9033	11/10/21	VOR–A, Amdt 16A.
30–Dec–21 ..	SC	Columbia	Columbia Metro	1/9035	11/10/21	RNAV (GPS) RWY 29, Amdt 1C.
30–Dec–21 ..	SC	Columbia	Columbia Metro	1/9038	11/10/21	RNAV (GPS) RWY 23, Amdt 2B.
30–Dec–21 ..	SC	Columbia	Columbia Metro	1/9041	11/10/21	RNAV (GPS) RWY 11, Amdt 1C.
30–Dec–21 ..	SC	Columbia	Columbia Metro	1/9044	11/10/21	RNAV (GPS) RWY 5, Amdt 2C.
30–Dec–21 ..	SC	Columbia	Columbia Metro	1/9046	11/10/21	ILS OR LOC RWY 29, Amdt 3I.

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
30–Dec–21 ..	SC	Columbia	Columbia Metro	1/9048	11/10/21	ILS OR LOC RWY 11, Amdt 15A.
30–Dec–21 ..	TX	Fredericksburg	Gillespie County	1/9053	11/10/21	VOR/DME–A, Amdt 3B.
30–Dec–21 ..	CA	Riverside	Riverside Muni	1/9359	11/5/21	RNAV (GPS) RWY 9, Amdt 2C.
30–Dec–21 ..	CA	Riverside	Riverside Muni	1/9373	11/5/21	ILS OR LOC RWY 9, Amdt 8D.
30–Dec–21 ..	NH	Haverhill	Dean Meml	1/9780	9/3/21	RNAV (GPS) RWY 19, Orig.

[FR Doc. 2021–27055 Filed 12–14–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA–2021–N–0583]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Nonimplanted Nerve Stimulator for Functional Abdominal Pain Relief

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the nonimplanted nerve stimulator for functional abdominal pain relief into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the nonimplanted nerve stimulator for functional abdominal pain relief's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective December 15, 2021. The classification was applicable on June 7, 2019.

FOR FURTHER INFORMATION CONTACT: Pamela Scott, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4208, Silver Spring, MD 20993–0002, 301–796–5433, *PamelaD.Scott@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the nonimplanted nerve stimulator for functional abdominal pain relief as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On October 25, 2018, Innovative Health Solutions, Inc. submitted a request for De Novo classification of the IB-Stim. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify 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 establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA