May 29, 2020

Mr. Ken Ryder
Senior Director, Global Regulatory Affairs
Abiomed, Inc.
22 Cherry Hill Drive
Danvers, MA 01923

Dear Mr. Ryder:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of the Impella RP System[1] (hereafter "Impella RP") intended to be used by healthcare providers (HCP) in the hospital setting for providing temporary right ventricular support for up to 14 days in critical care patients[2] with a body surface area ≥1.5 m^2, for the treatment of acute right heart failure or decompensation caused by complications related to Coronavirus Disease 2019 (COVID-19), including pulmonary embolism (PE).

On February 4, 2020, pursuant to section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19.[3] Pursuant to section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, during the COVID-19 outbreak, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.[4]

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[1] The Impella RP is currently approved under PMA P170011, product code PYX, under 21 CFR 870.4360. The approved indication is for providing temporary right ventricular support for up to 14 days in patients with a body surface area ≥1.5 m^2, who develop acute right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery. This EUA authorizes the emergency use of the Impella RP to include use of the device on patients who develop acute right heart failure or decompensation caused by complications related to Coronavirus Disease 2019 (COVID-19), including pulmonary embolism (PE).

[2] "Critical care patients" refers to patients in the intensive care unit (ICU).

[3] U.S. Department of Health and Human Services, Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3. 85 FR 7316 (February 7, 2020).

[4] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 17335 (March 27, 2020).

There are no FDA approved or cleared devices available for use by HCP in the hospital setting specifically for treating acute right heart failure or decompensation caused by complications related to COVID-19, including PE. The Impella PR is FDA-approved (PMA approval P170011) to provide temporary right ventricular support for acute heart failure caused by four other conditions that can cause acute heart failure or decompensation, specifically: (1) left ventricular assist device implantation, (2) myocardial infarction, (3) heart transplant, or (4) open-heart surgery. There is evidence that COVID-19 can manifest a prothrombotic environment in patients and in turn result in acute intravascular thrombosis, which may lead to acute PE and subsequent right ventricular failure or decompensation. This manifestation or condition is substantively different than the four other conditions that may result in acute right heart failure or decompensation for which FDA approved Impella PR to treat, and therefore, is a different indication requiring FDA-authorization. However, based on extrapolation of data from the approved indication and reported clinical experience, FDA has concluded that the Impella RP may be effective at providing temporary right ventricular support for the treatment of acute right heart failure or decompensation caused by COVID-19 complications, including PE, warranting expansion of the intended use of the Impella PR for this purpose during the public health emergency.

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act are met, I am authorizing the emergency use of the Impella RP, as described in the Scope of Authorization (Section II) and pursuant to the Conditions of Authorization (Section IV) of this letter.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the Impella RP, as described in the Scope of Authorization (Section II) of this letter meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. SARS-CoV-2, the disease that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Impella RP may be effective in providing temporary right ventricular support for up to 14 days in critical care patients with a body surface area ≥ 1.5 m^2, for the treatment of acute right heart failure or decompensation caused by complications related COVID-19, including PE, and that the known and potential benefits of the Impella RP, for such use, outweigh the known and potential risks; and,

3. There is no adequate, approved, and available alternative to the emergency use of the Impella RP for treating acute right heart failure or decompensation caused by complications related to COVID-19, including PE.[5]

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the Impella RP by HCP in the hospital setting for providing temporary right ventricular support for up to 14 days in critical care patients with a body surface area ≥1.5 m^2, for the treatment of acute right heart failure or decompensation caused by complications related to COVID-19, including PE. The Impella RP is not intended for use for patients with the following conditions:

- Disorders of the pulmonary artery wall that would preclude placement or correct positioning of the Impella RP catheter
- Mechanical heart valves, severe valvular stenosis or valvular regurgitation of the tricuspid or pulmonary valve
- Mural thrombus of the right atrium or vena cava
- Anatomic conditions precluding insertion of the pump
- Presence of a vena cava filter or caval interruption device, unless there is clear access from the femoral vein to the right atrium that is large enough to accommodate a 22-French gauge (Fr) catheter

The Authorized Impella RP

The Impella RP is a minimally invasive, miniaturized percutaneous circulatory support system for the right ventricle.

The Impella RP is comprised of the following components:

- an Impella RP Catheter and its accessories, including a 23-Fr Peel-away Introducer kit (Oscor Medical, cleared under K122084) and a 0.025″ placement guidewire (Boston Scientific, cleared under K935997)
- an Automatic Impella Controller (AIC)
- an Impella Purge Cassette
- a reusable cart for the AIC

The Impella RP requires the use of the following components and materials, which are not provided but commonly used in the hospital setting, as described in the authorized Impella RP

[5] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

Instructions for Use:

- 5-8 Fr introducer for initial femoral vein access[6]
- Femoral length Swan-Ganz or other flow-directed, balloon-tipped catheter appropriate for delivery of the guidewire to the pulmonary artery[7]
- Sterile dextrose solution (typically 5% dextrose in water with 25 or 50 International Units (IU)/millilter (mL) of heparin)

The above described Impella RP, is authorized to be accompanied with labeling, entitled "Impella RP System with the Automated Impella Controller Circulatory Support System Instructions for Use & Clinical Reference Manual" (available at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations), together with the following product-specific information pertaining to emergency use, which is required to be made available to HCP and patients, respectively:

- Fact Sheet for Healthcare Providers: Emergency Use of Impella RP System During the COVID-19 Outbreak
- Fact Sheet for Patients: Emergency Use of Impella RP System During the COVID-19 Outbreak

The above described product, when accompanied with the Instructions for Use (identified above) and the two Fact Sheets (collectively referred to as "authorized labeling") is authorized to be distributed under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the Impella RP when used as described in the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of this product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized Impella RP may be effective as described in and when used consistently with the Scope of Authorization of this letter (Section II), pursuant to section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that the authorized Impella RP, as described in the Scope of Authorization of this letter (Section II), meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the Impella RP must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III. Subject to the terms and conditions of this EUA and under the circumstances set forth in the Secretary of HHS's determination under section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the Impella RP

[6] Product code: DYB; regulation number: 870.1340, catheter introducer
[7] Product code: DYG; regulation number: 870.1240, flow-directed catheter

described above is authorized for use by HCP in the hospital setting for providing temporary right ventricular support for up to 14 days in critical care patients with a body surface area ≥1.5 m^2, for the treatment of acute right heart failure or decompensation caused by complications related to COVID-19, including PE.

III. Conditions of Authorization

Pursuant to section 564(e) of the Act, I am establishing the following conditions on this authorization:

Abiomed, Inc., as Sponsor of Authorized Product

A. Abiomed, Inc. must comply with the labeling requirements under 21 CFR 801 Subpart A (general labeling provisions) and 21 CFR 801.109 (labeling for prescription devices), as well as those described in Section II of this letter, Scope of Authorization. As such, compliance with unique device identification regulations (see Subpart B of 21 CFR Part 801) is not required under this EUA.

B. Abiomed, Inc. must comply with applicable current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the authorized devices

C. Abiomed, Inc. will make the Impella RP available with authorized labeling. Abiomed, Inc. may request changes to the authorized labeling. Such changes require review and concurrence from Office of Health Technology 2 (OHT2)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH).

D. Abiomed, Inc. may request changes to the Scope of Authorization (Section II in this letter) of the authorized Impella RP. Such requests will be made by Abiomed, Inc., in consultation with, and require concurrence of OHT2/OPEQ/CDRH and the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC).

E. Abiomed, Inc. may request changes to any components or materials. Such requests will be made in consultation with and require concurrence of OHT2/OPEQ/CDRH.

F. Abiomed, Inc. will have process in place for reporting adverse events of which they become aware and will report to FDA under 21 CFR Part 803. Abiomed, Inc. will establish a process to collect adverse event information from healthcare facility customers.

G. Abiomed, Inc. will notify FDA of any authorized distributor(s)[8] of the Impella RP,

[8] "Authorized Distributor(s)" are identified by Abiomed, Inc. in an EUA submission as an entity allowed to distribute the device.

including the name, address, and phone number of any authorized distributor(s), and provide authorized distributor(s) with a copy of this EUA and any updates.

Abiomed, Inc. and any Authorized Distributor(s)

H. Abiomed, Inc. and authorized distributors will distribute the authorized Impella RP with the authorized labeling only to healthcare facilities with HCP who are adequately equipped, trained, and capable of using the Impella RP according to the criteria set forth by Abiomed, Inc.

I. Abiomed, Inc. and authorized distributors will make authorized labeling available on their websites.

J. Authorized distributors will make Abiomed, Inc. aware of any adverse events of which they become aware.

K. Through a process of inventory control, Abiomed, Inc. and authorized distributors will maintain records of the healthcare facilities to which they distribute the Impella RP and the number of each product they distribute.

L. Abiomed, Inc. and authorized distributor(s) are authorized to make available additional information relating to the emergency use of the product that is consistent with, and does not exceed, the terms of this letter of authorization.

M. Abiomed, Inc. and authorized distributor(s) will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

Healthcare Facilities

N. Healthcare facilities using the authorized Impella RP must make available to patients the accompanying Patient Fact Sheet and make available to the HCP the accompanying Healthcare Provider Fact Sheet.

O. Healthcare facilities using the Impella RP must make Abiomed, Inc., and FDA aware of any adverse events under 21 CFR Part 803.

P. Healthcare facilities will ensure HCP using the Impella RP are adequately equipped, trained, capable, and will maintain records of device usage.

Conditions Related to Advertising and Promotion

Q. All descriptive printed matter, including advertising and promotional materials relating to the use of the authorized Impella RP shall be consistent with the authorized labeling, as

well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

R. No descriptive printed matter, including advertising or promotional materials relating to the use of the authorized Impella RP may represent or suggest that this product is safe or effective for providing temporary right ventricular support for up to 14 days in critical care patients with a body surface area ≥1.5 m^2, for the treatment of acute right heart failure or decompensation caused by complications related to COVID-19, including PE.

S. All descriptive printed matter, including advertising and promotional materials relating to the authorized use of the Impella RP shall clearly and conspicuously state that:

- The Impella RP has neither been cleared or approved for the indication of providing temporary right ventricular support for up to 14 days in critical care patients with a body surface area ≥1.5 m^2, for the treatment of acute right heart failure or decompensation caused by complications related to COVID-19, including PE;

- The Impella RP has been authorized for the above emergency use by FDA under an EUA; and,

- The Impella RP has been authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the Impella RP is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,

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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures