UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

VASCULAR SOLUTIONS LLC; TELEFLEX INNOVATIONS S.á R.L., ARROW INTERNATIONAL, INC., AND TELEFLEX LLC, Plaintiffs/ Counterclaim Defendants, v. MEDTRONIC, INC. AND MEDTRONIC VASCULAR, INC., Defendants/ Counterclaim Plaintiffs.	Court File No. 0:19-cv-1760 (PJS/TNL) **DECLARATION OF HEATHER S. ROSECRANS**

I, Heather S. Rosecrans, declare as follows:

1. I have been retained by Defendants Medtronic, Inc. and Medtronic Vascular, Inc. (collectively, "Medtronic") to provide my expert opinions in this matter. I make this declaration in opposition to the motion for a preliminary injunction filed by Plaintiffs Vascular Solutions LLC, Teleflex Innovations S.a.r.l, Arrow International, Inc. and Teleflex LLC (collectively, "Teleflex"). If called to testify, I could and would testify to the following facts and opinions.

I. Background and Qualifications

2. My educational background and professional history are summarized in the below paragraphs. My curriculum vitae is attached as Appendix A to this declaration.

A. Education

3. In 1976, I was awarded a Bachelor's Degree from Pfeiffer College where I majored in Biology.

B. FDA Career

4. Shortly after graduation, I began a 33-year career at FDA – the majority of which was spent working in what is now known as the Center for Devices and Radiological Health ("CDRH" or "the Center"). CDRH is responsible for regulating firms that manufacture, repackage, re-label, and/or import medical devices for commercial distribution in the United States.

5. From 1978 to 1980, I held the position of Biologist in the Division of Clinical Laboratory Devices in the premarket review office at the Bureau of Medical Devices (now CDRH). My principal responsibilities included reviewing and tracking of premarket notification submissions ("510(k)s") and Premarket Approval Applications ("PMAs"). Additionally, I was responsible for researching, interpreting, and drafting proposed and final microbiology devices classification regulations.[1]

6. In 1980, I was assigned to the PMA Section in the premarket review office where I served as a Consumer Safety Officer. The PMA Section (later renamed "PMA Staff" and now called Division of Regulatory Programs 1 (Submission Support)) oversees and coordinates the administrative and regulatory review of PMAs, product development protocols ("PDPs"), Humanitarian Device Exemptions ("HDE") and associated submissions such as Environmental Assessments, Color Additive Petitions,

[1] See 21 C.F.R. Part 866 (final regulations).

Device Master Files, patent term extension petitions, and postapproval reports under Section 515 of the Federal Food, Drug, and Cosmetic Act ("FDCA" or "the Act").[2]

7. The CDRH PMA Section was in the newly organized Program Management Staff ("PMS") and later called the Program Operations Staff ("POS") in the Office of Device Evaluation ("ODE") at CDRH. I held the position of Consumer Safety Officer in the PMA Section from 1980 until 1987. In this role, I was responsible for overseeing the review of PMAs and PDPs to ensure that the applications were reviewed in accordance with the statutory criteria and established regulations, procedures, policies, and time frames as well as participating in the development of related regulations, procedures, policies, and time frames. During this time, I was also responsible for developing appropriate educational materials and other guidance regarding PMA-related activities for use by CDRH, including the review staff, other FDA medical product Centers, and other stakeholders. I also provided training on PMAs and PDPs for the agency as well as for external stakeholders.

8. In 1987, I joined the 510(k) Section of POS in ODE. The 510(k) Section (now known as the "510(k) Staff") is responsible for overseeing and coordinating the regulatory and administrative review of 510(k) submissions in CDRH, assisting other Centers at FDA with 510(k)s, as well as providing information on the 510(k) program to other regulatory agencies and stakeholders.

[2] FDCA § 515, 21 U.S.C. § 360e.

9. From 1987 until 1992, I served as a Consumer Safety Officer in the 510(k) Section, where I provided regulatory, administrative, and policy oversight of CDRH's review of 510(k)s. While serving in the 510(k) Section, I also assisted in writing the interim and final rules titled, "Medical Devices; Substantial Equivalence; 510(k) Summaries and 510(k) Statements, Class III Summary and Certification; Confidentiality of Information."[3] Additionally, I established the process for the rescission of 510(k) substantial equivalence decisions and worked on a proposed rule for the process.

10. From 1992 to 2010, I held several changing titles that all involved the same job responsibilities and level of seniority. These titles included: (1) Acting Section Chief of the 510(k) Section; (2) Supervisory Consumer Safety Officer of the 510(k) Staff; and (3) Director of the 510(k) Staff. In this role, I was the primary contact on issues related to the implementation of the 510(k) requirements under the Safe Medical Devices Act of 1990 ("SMDA")[4], 510(k) Summaries, 510(k) Statements, and Class III Certifications and Summaries to ensure the uniform interpretation of the law.[5] I supervised the programmatic review of 510(k) submissions and 513(g) requests, device classification processes, petitions for reclassification, petitions for Class II exemption from 510(k), and other regulatory requirements. Additionally, I was responsible for drafting regulations regarding the above areas. I also trained CDRH and FDA's Center for Biologics

[3] See 59 Fed. Reg. 64,295 (Dec. 14, 1994) (final rule); 57 Fed. Reg. 18,062 (Apr. 28, 1992) (interim rule).

[4] See Pub. L. No. 101-629 (1990).

[5] Although the law was passed in 1990, this requirement was not implemented until 1992.

Evaluation and Research ("CBER") staff on statutory and regulatory requirements as well as procedures and policies—including any new regulations, policies, or procedures. I coordinated the regulatory review process of 510(k) submissions, including device determinations, between the CDRH premarket review staff and the CDRH Office of Compliance staff. I also managed any necessary coordination with the Office of Combination Products ("OCP") (prior to 2002 when OCP was established, FDA's Ombudsman handled combination products), the Center for Drug Evaluation and Research ("CDER"), and CBER for these programs.

11. In 2009, I served as the CDRH lead in responding to the Government Accountability Office ("GAO") study of the 510(k) program. Also in 2009, I served as a point of contact when FDA commissioned the Institute of Medicine ("IOM") to undertake an assessment of the 510(k) program to determine what, if any, changes should be made to the program.

12. During the IOM's 18-month review of the 510(k) program, I provided training to the IOM review committee to educate members on the 510(k) program at their first public meeting in March 2010. My presentation to the IOM committee was titled, "Understanding the Premarket Notification (510(k)) Process: History from 1976 to 2010." As a member of the CDRH 510(k) Working Group, I also participated in the internal evaluation of the 510(k) program and subsequent "Plan of Action for Implementation of 510(k) and Science Recommendations," which was published in draft in August 2010.

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