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12 Attorneys for Defendant/Counterclaimant NUVASIVE, INC.

14 UNITED STATES DISTRICT COURT

15 SOUTHERN DISTRICT OF CALIFORNIA

16 WARSAW ORTHOPEDIC, INC.;
17 MEDTRONIC SOFAMOR DANEK U.S.A.,
INC.; MEDTRONIC PUERTO RICO
18 OPERATIONS CO.; AND OSTEOTECH, INC.

19 Plaintiff

20 v.

21 NUVASIVE, INC.,

22 Defendant

Case No. 3:12-cv-02738-CAB-MDD

**DEFENDANT NUVASIVE, INC.’S
ANSWER TO PLAINTIFFS’ FIRST
AMENDED COMPLAINT FOR PATENT
INFRINGEMENT AND
COUNTERCLAIMS**

JURY TRIAL DEMANDED

Judge: Hon. Cathy Ann Bencivengo
Courtroom: 2

24 Defendant NuVasive, Inc. (“NuVasive”), by and through its attorneys, hereby answers the
25 First Amended Complaint for Patent Infringement of Plaintiffs Warsaw Orthopedic, Inc.
26 (“Warsaw”), Medtronic Sofamor Danek USA, Inc. (“Sofamor Danek USA”), Medtronic Puerto
27 Rico Operations Co. (“MPROC”), and Osteotech, Inc. (“Osteotech”) (collectively, “Plaintiffs”).
28

1 NuVasive denies each and every allegation in the First Amended Complaint that is not expressly
2 admitted below.

3 **PARTIES, JURISDICTION, AND VENUE**

4 1. On information and belief, NuVasive admits that Warsaw is an Indiana corporation,
5 with its principal place of business in Warsaw, Indiana. NuVasive is without knowledge or
6 information sufficient to admit or deny the remaining allegations of paragraph 1 and therefore
7 denies them.

8 2. On information and belief, NuVasive admits that Sofamor Danek USA is a
9 Tennessee corporation, with its principal place of business in Memphis, Tennessee. NuVasive is
10 without knowledge or information sufficient to admit or deny the remaining allegations of
11 paragraph 2 and therefore denies them.

12 3. On information and belief, NuVasive admits that MPROC is a Cayman Islands
13 corporation with its principal place of business in Humacao, Puerto Rico. NuVasive is without
14 knowledge or information sufficient to admit or deny the remaining allegations of paragraph 3 and
15 therefore denies them.

16 4. On information and belief, NuVasive admits that Osteotech is a Delaware
17 corporation with its principal place of business in Eatontown, New Jersey. NuVasive is without
18 knowledge or information sufficient to admit or deny the remaining allegations of paragraph 4 and
19 therefore denies them.

20 5. NuVasive admits the allegations in paragraph 5.

21 6. NuVasive admits that the Complaint purports to state claims arising under the
22 patent laws of the United States, Title 35 of the United States Code.

23 7. NuVasive admits the allegations in paragraph 7.

24 8. NuVasive admits that it transacts business in the United States Federal Judicial
25 District for the Southern District of California. NuVasive denies the remaining allegations of
26 paragraph 8.

27 9. NuVasive admits the allegations in paragraph 9.

28

PLAINTIFFS' COUNT I

1
2 10. In response to paragraph 10, NuVasive incorporates its responses to paragraphs 1-9
3 as if fully set forth herein.

4 11. NuVasive admits that U.S. Patent No. 8,021,430 (the “‘430 patent”) is entitled
5 “Anatomic Spinal Implant Having Anatomic Bearing Surfaces” and that it issued on September
6 20, 2011. NuVasive is without knowledge or information sufficient to admit or deny the
7 remaining allegations of paragraph 11 and therefore denies them.

8 12. NuVasive denies the allegation in paragraph 12.

9 13. NuVasive denies the allegation in paragraph 13.

10 14. NuVasive denies the allegation in paragraph 14.

PLAINTIFFS' COUNT II

11
12 15. In response to paragraph 15, NuVasive incorporates its responses to paragraphs 1-9
13 as if fully set forth herein.

14 16. NuVasive admits that U.S. Patent No. 5,676,146 C2 (the “‘146 patent”) is entitled
15 “Surgical Implant Containing A Resorbable Radiopaque Marker And Method Of Locating Such
16 Within A Body,” and that it issued on December 25, 2007. NuVasive further admits that the
17 original application to the ’146 patent initially issued as a patent on October 14, 1997, and that
18 reexamination certificates for the ’146 patent were issued on April 18, 2000 and December 25,
19 2007. NuVasive is without knowledge or information sufficient to admit or deny the remaining
20 allegations of paragraph 16 and therefore denies them.

21 17. NuVasive is without knowledge or information sufficient to admit or deny the
22 allegations of paragraph 17 and therefore denies them.

23 18. NuVasive is without knowledge or information sufficient to admit or deny the
24 allegations of paragraph 18 and therefore denies them.

25 19. NuVasive is without knowledge or information sufficient to admit or deny the
26 allegations of paragraph 19 and therefore denies them.

27 20. NuVasive denies the allegation in paragraph 20.

28 21. NuVasive denies the allegation in paragraph 21.

1 22. NuVasive denies the allegation in paragraph 22.

2 23. NuVasive denies the allegation in paragraph 23.

3 24. NuVasive admits that it was served with Plaintiffs' original Complaint for Patent
4 Infringement and Jury Demand on or about August 21, 2012. NuVasive is without knowledge or
5 information sufficient to admit or deny the remaining allegations in paragraph 24 and therefore
6 denies them.

7 25. NuVasive denies the allegation in paragraph 25.

8 26. NuVasive denies the allegations in paragraph 26.

9 27. NuVasive denies the allegation in paragraph 27.

10 28. NuVasive denies the allegation in paragraph 28.

11 **PLAINTIFFS' COUNT III**

12 29. In response to paragraph 29, NuVasive incorporates its responses to paragraphs 1-
13 12 as if fully set forth herein.

14 30. NuVasive admits that U.S. Patent No. 8,251,997 (the "997 patent") is entitled "A
15 Method For Inserting An Artificial Implant Between Two Adjacent Vertebrae Along A Coronal
16 Plane" and that it issued on August 28, 2012 from U.S. Application No. 13/306,586 ("the '583
17 application"). NuVasive is without knowledge or information sufficient to admit or deny the
18 remaining allegations of paragraph 30 and therefore denies them.

19 31. NuVasive denies the allegation of paragraph 31.

20 32. NuVasive denies the allegation of paragraph 32.

21 33. NuVasive denies the allegation of paragraph 33.

22 34. NuVasive admits that an Opposition and Petition Under 37 C.F.R. § 1.183 was
23 filed with the United States Patent & Trademark Office in the *inter partes* reexamination of U.S.
24 Patent No. 7,207,949. The Opposition and Petition stated in a footnote that the claims of the '583
25 application were allowed and the patent would issue shortly. NuVasive denies the remaining
26 allegations in paragraph 34.

27 35. NuVasive denies the allegation in paragraph 35

28 36. NuVasive denies the allegation in paragraph 26.

1 37. NuVasive denies the allegations of paragraph 37.

2 38. NuVasive admits that some of its marketing materials read “the CoRoent XL
3 family of implants. Designed specifically for the eXtreme Lateral Interbody Fusion (XLIF)
4 procedure,” among other things. NuVasive denies the remaining allegations in paragraph 38.

5 39. NuVasive admits that some of its marketing materials read “fourth generation XLIF
6 access system” and “designed to deliver safe and reproducible XLIF outcomes by combining
7 *Strength, Precision, Fluoro-visibility, and Integrated Neuromonitoring,*” among other things.
8 NuVasive denies the remaining allegations of paragraph 39.

9 40. NuVasive denies the allegations in paragraph 40.

10 41. NuVasive denies the allegations in paragraph 41.

11 **PLAINTIFFS’ PRAYER FOR RELIEF**

12 In response to Plaintiffs’ Prayer for Relief, NuVasive denies that Plaintiffs are entitled to
13 the relief requested or any other relief.

14 **AFFIRMATIVE DEFENSES**

15 NuVasive asserts the following affirmative defenses in response to Plaintiffs’ First
16 Amended Complaint. NuVasive reserves the right to assert additional affirmative defenses as they
17 become known through discovery and the course of the litigation.

18 **First Affirmative Defense**

19 42. NuVasive has not infringed and does not currently infringe, either directly or
20 indirectly, any valid, enforceable claim of the ’430, ’146, and ’997 patents.

21 **Second Affirmative Defense**

22 43. The ’430, ’146, and ’997 patents are invalid for failure to satisfy the requirements
23 of 35 U.S.C. § 101 *et seq.*, including, without limitation, sections 101, 102, 103, and 112.

24 **Third Affirmative Defense**

25 44. One or more of the plaintiffs lack standing to assert infringement of the ’430, ’146,
26 and ’997 patents.

27 **COUNTERCLAIMS**

28 NuVasive, for its counterclaims against Plaintiffs, states and alleges as follows:

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