Watson Guide IP, LLC
Patent No. 11,806,209 – PGR2024-00040

Filed on behalf of Watson Guide IP, LLC
By: Marc Karish
Bruce Chapman
Orbit IP, LLP
11400 W. Olympic Blvd, Suite 200
Los Angeles, CA 90064
Telephone (310) 887-1333
Email: mkarish@orbitip.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

3D DIAGNOSTIX, INC.,

Petitioner,

v.

WATSON GUIDE IP, LLC

Patent Owner

Case PGR2024-00040
U.S. Patent No. 11,806,209

DECLARATION OF ALAN BANKS

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I, Alan Banks, of Akron, Ohio, declare as follows:

VII. BACKGROUND AND QUALIFICATIONS

1. I have been the President of GuidedSMILE LLC ("GuidedSMILE") since that company began operation on January 1, 2024. GuidedSMILE was spun off by ROE Dental Laboratory, Inc. ("ROE") to handle the CHROME GuidedSMILE product described below.

2. I was employed by ROE from 2001 to 2023. I focused on ROE's guided surgery products since 2005. In that role, I provided product support to dentists and educational programs for dentists focused on guided surgery, as well as helped to advance ROE's guided surgery business through both management and product development. In that capacity, I have consulted extensively with many dentists and oral surgeons regarding various surgical techniques for full arch restoration, including difficulties with those techniques, and observed many full arch restoration surgeries.

VIII. LONG FELT NEED

3. From my experience, I learned that there was a need for a guided surgical product to improve the efficiency and accuracy of full-arch surgery and restoration. Full arch procedures occurs when the existing teeth of a patient are removed from either the maxillary or mandibular jaw, followed by implantation of

several implants that are placed in that jaw, and a prothesis/denture replicating the desired teeth on that jaw is attached to the implants.

4. Initially, dentists and oral surgeons performed full arch restoration surgery in a procedure called "freehand." This meant that the surgeon would place the implant without a surgical guide and a prothesis/denture (teeth) would be attached to the implants. This approach lacked predictability with respect to proper alignment between the implants with the prosthesis/denture.

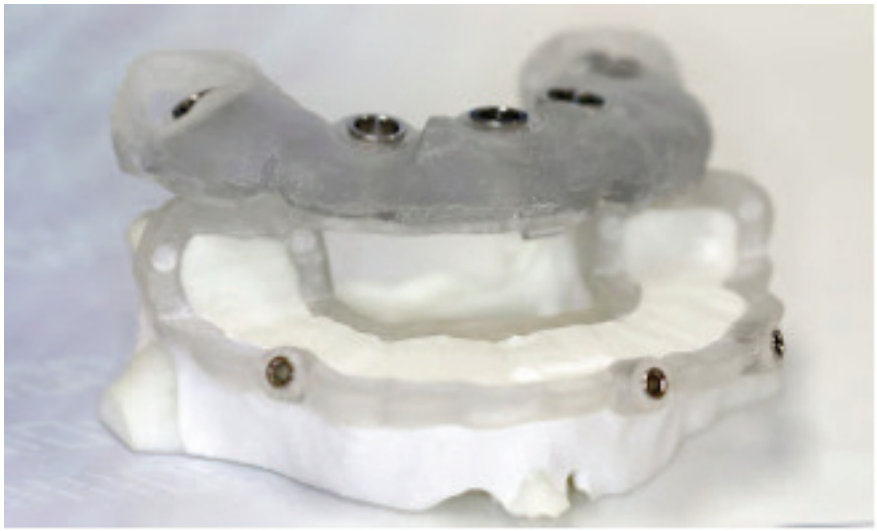
5. The initial guided surgical products relied on unpredictable surfaces for installation and failed to solve this problem. These products included tooth supported guides that relied on teeth that were not necessarily stable, tissue supported guides that were not predictable, and bone supported guides which relied on an imperfect surface to locate the guides. These products could lead to the same misalignment between implants and prothesis/denture that plagued the freehand technique. The initial bone-supported stackable guides also lacked predictability. For example, the nSequence guides relied on relatively small tooth engagement with the opposite jaw from the guides for positioning, requiring the patient to bite down during surgery, which on a sedated patient was not possible and led to inaccuracies.

6. As a result, from the beginning of full arch restoration surgery, an effective guided surgical product was needed to accomplish this procedure with

higher degrees of accuracy and predictability compared to the freehand placement of implants or the early guided surgical products.

IX. FAILURE OF OTHERS

7. In an attempt to satisfy this need, ROE launched the CombiGuide in 2015. The 2015 version of CombiGuide included a bone mounted guide pinned to the jawbone that could be used for full arch surgery. The original CombiGuide did not have mouthpiece, which in CHROME GuidedSMILE we call a pin guide, for positioning the CombiGuide and locating the pins used with the CombiGuide. Despite significant marketing efforts, the CombiGuide was not a commercial success for ROE. A picture of this version of CombiGuide is shown below.

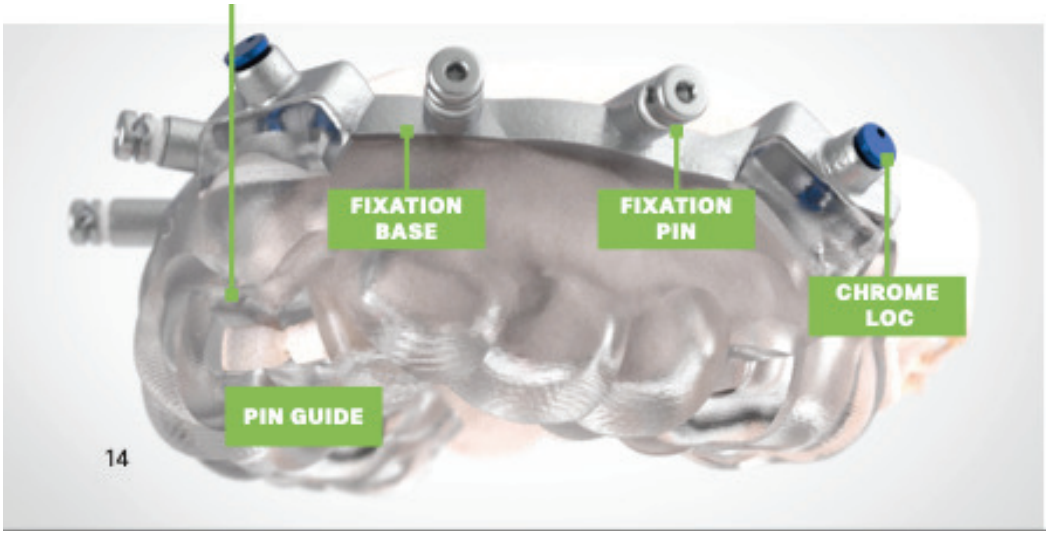


X. COMMERCIAL SUCCESS

8. Because CombiGuide was not a commercial success, ROE exclusively licensed CHROME GuidedSmile from Watson Guide IP, LLC.

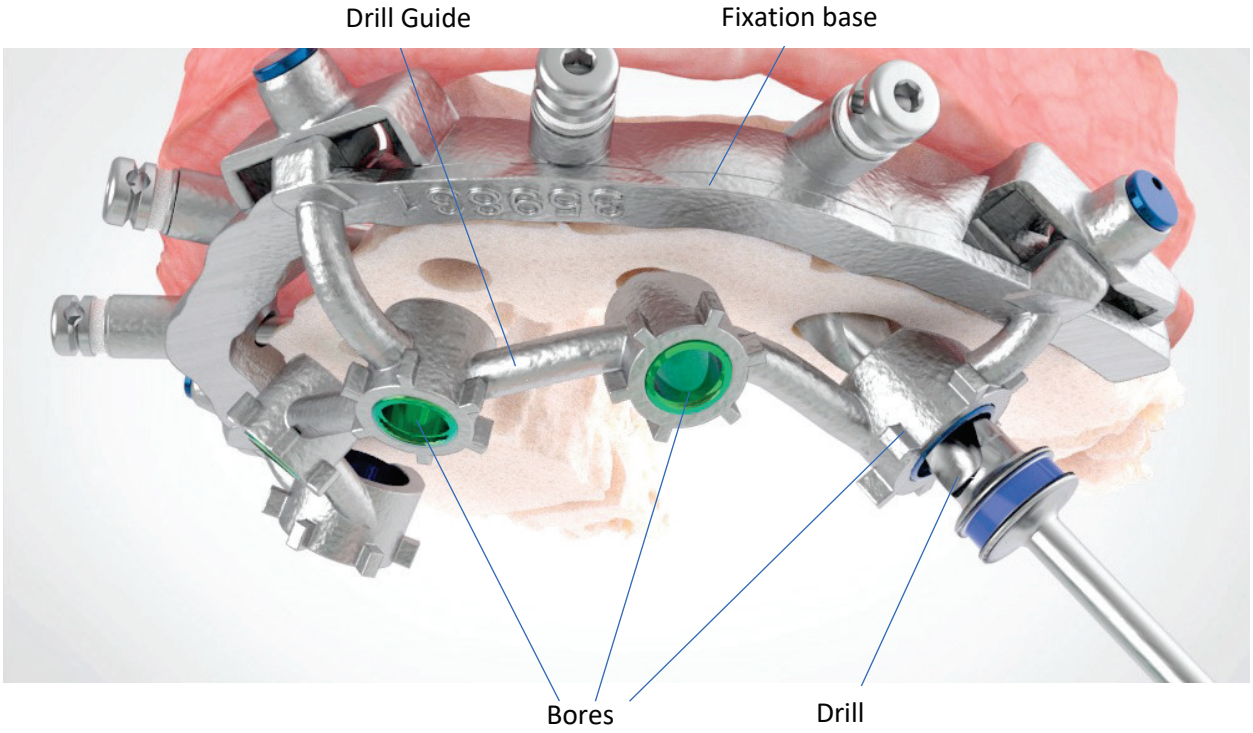
CHROME GuidedSmile is a system and method for installing a multi-tooth dental prosthesis for the maxillary or mandibular jaw in a patient's mouth. The CHROME GuidedSmile product is marked with a link to the patent numbers for the licensed Watson Guide IP, LLC patents, including U.S. Patent No. 11,806,209.

9. CHROME GuidedSmile includes a fixation base that can be attached to a mouthpiece (which we call a pin guide). The mouthpiece surrounds the teeth of the patient on the jaw upon which the fixation base is being installed. The mouthpiece ensures that the fixation base is properly positioned on the jaw and pins placed through openings in the fixation base are properly located in the jaw.



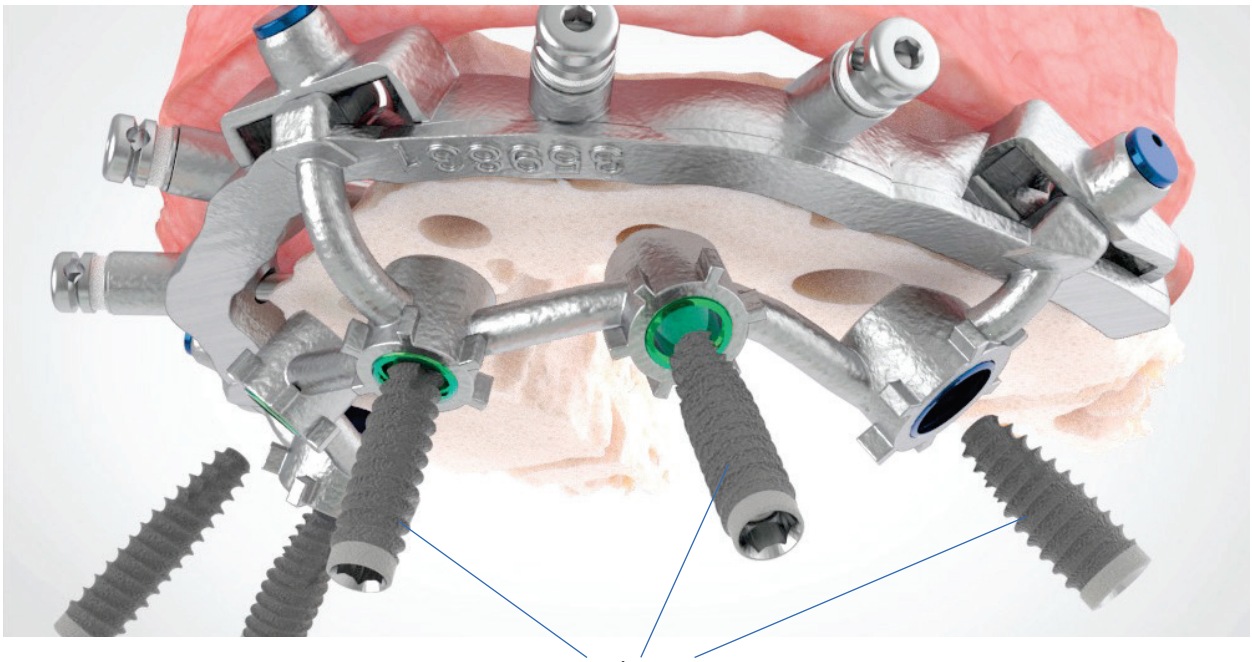
10. The patient's gums are cut, and a facial flap is created to expose the jawbone. After, the mouthpiece (pin guide) and fixation base are inserted, and held into place while the fixation pins are placed in the jaw. The mouthpiece is then

removed, and any remaining teeth or dental fixtures are also removed. With the jawbone is exposed, a top surface of the bone is reduced to form a flat surface. Once the jawbone has been reduced, a drill guide (which we call an osteotomy guide) can be attached to the fixation base, as shown below and holes drilled through bores in the drill guide in predetermined locations so that implants can be properly located.



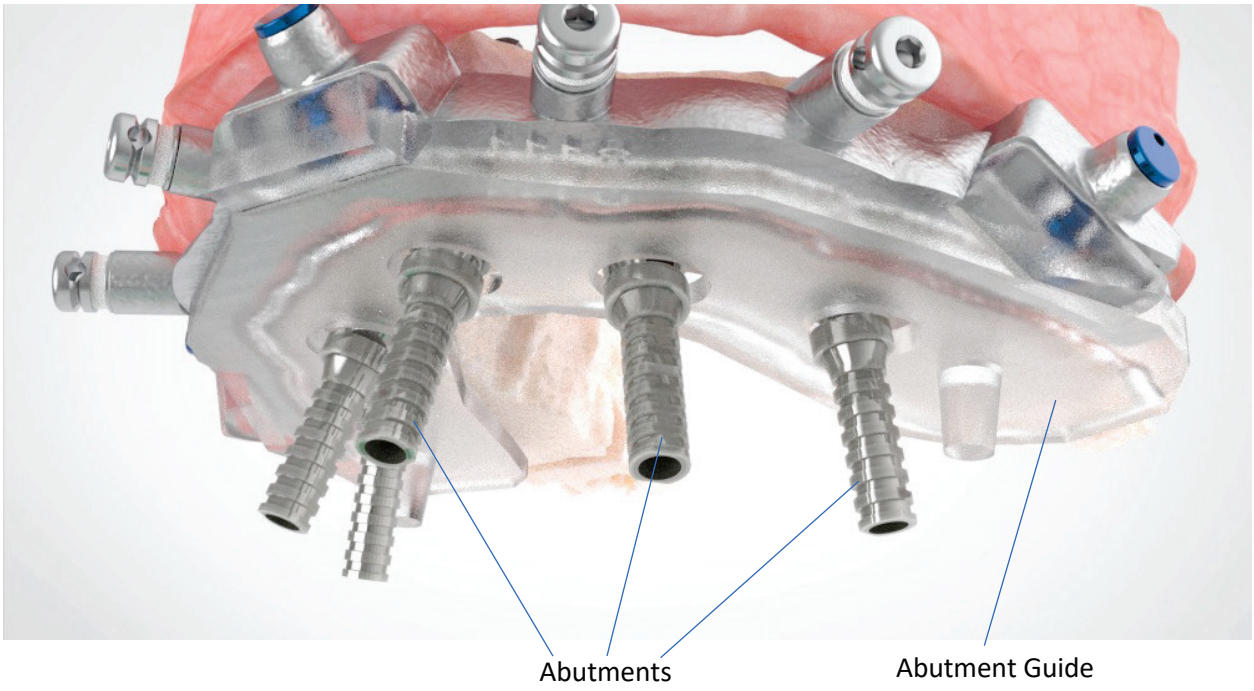
11. Once holes have been drilled using the osteotomy guide, implants are placed in the holes. In some cases, the implants can be placed in the implant holes

through the osteotomy guide, and in other cases the osteotomy guide is removed prior to placement of the implants.



12. Once the osteotomy guide is removed from the fixation base, an abutment guide, shown below, can be attached to the fixation base in order to guide

placement of abutments and ultimately the prothesis.



13. A temporary prosthesis is included with CHROME GuidedSmile. Once the abutments have been installed over the implants the prosthesis is installed onto the abutments.

14. The standard CHROME GuidedSMILE kit includes also includes a tooth model, bone model and reduced bone model. The tooth model can be used during the surgery to verify the fit of the mouthpiece (pin guide) before it is used on the patient. The bone model and reduced bone model can be used during the bone reduction to assist in visualizing the bone that needs to be removed. The tooth model, bone model and reduced bone model are not a significant reason why doctors choose to use CHROME GuidedSMILE. Use of CHROME GuidedSMILE is driven by the efficiency and accuracy provided by the series of guides used during surgery.

15. With the same marketing effort used to promote the CombiGuide, CHROME GuidedSMILE was immediately a successful product for ROE. ROE's sales of CHROME GuidedSmile are shown below.

16. Because of its success, ROE spun off GuidedSMILE in 2024 to be dedicated to the CHROME GuidedSmile product.

XI. PRAISE

17. After launching CHROME GuidedSMILE, ROE started to receive praise for the product. Specifically, Dentistry Today – the nation's leading clinical news magazine for dentists – gave CHROME GuidedSMILE eleven awards across five categories:

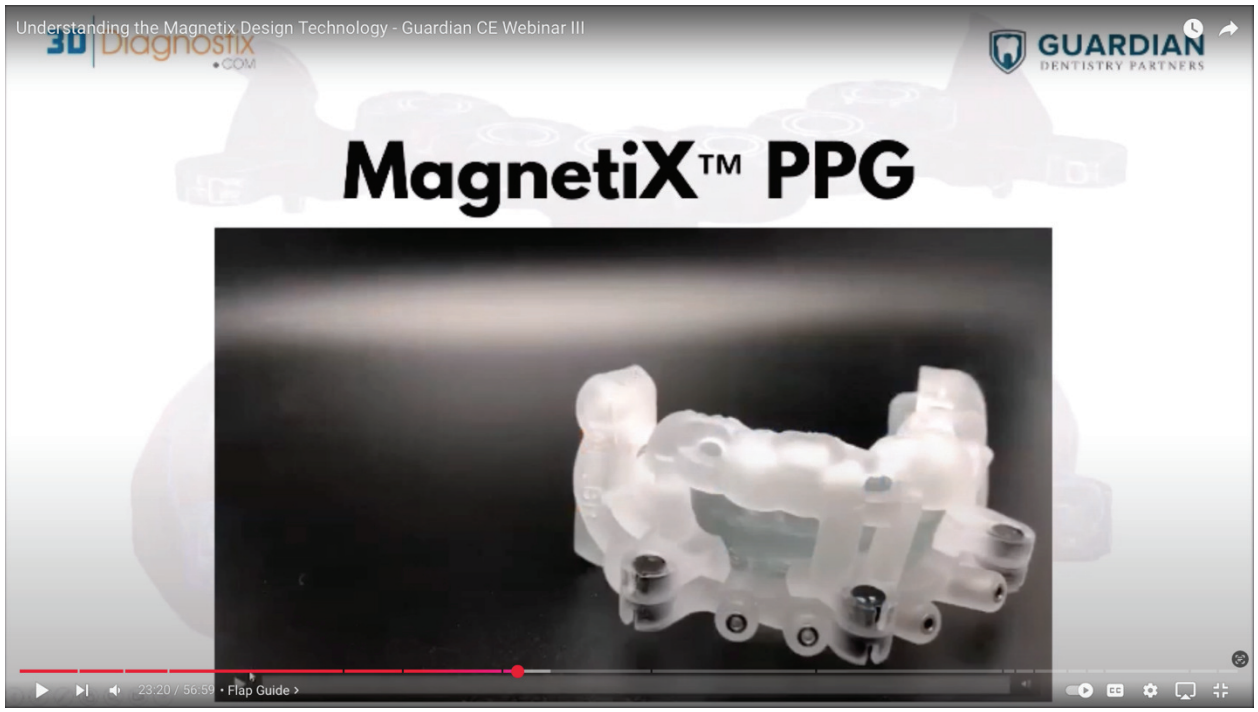
- Editors' Choice award winner - 2023, 2024
- Top Innovative Products Winner - 2023, 2024
- Innovation Spotlight Winner - 2023, 2024
- Top 100 Products Winner - 2022, 2023, 2024
- Top 25 Aesthetic/Restorative Products Winner - 2023, 2024

Additionally, CHROME GuidedSmile was given an award for Product or Innovation of the Year at the 2022 U.K. Dental Industry Awards, which recognize excellence in the U.K. dental industry.

XII. COPYING

18. Other companies have copied the CHROME GuidedSMILE product. For example, the petitioner, 3D Diagnostix, used to sell a guide where a mouthpiece did not attach to a fixation base for purposes of properly locating the fixation base, as shown below.

See https://www.youtube.com/watch?v=v7jfN0VQX8g at 22:40. After CHROME GuidedSmile was introduced, 3D Diagnostix changed its product to include a mouthpiece that attached to the fixation base to locate the fixation base, as shown below.



See https://www.youtube.com/watch?v=v7jfN0VQX8g at 23:20.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true and that such statements are made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

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Executed on April 21, 2025 at Independence, Ohio.

Alan Banks

CERTIFICATE OF SERVICE

The undersigned certifies that pursuant to 37 C.F.R. § 42.6(e), a true copy of the foregoing document was filed electronically and served via email to all parties in this proceeding at the addresses indicated:

Aaron R. Feigelson (Reg. No. 59,022) (lead counsel)

Wesley O. Mueller (Reg. No. 33,976) (backup counsel)

Leydig, Voit & Mayer, Ltd.

Two Prudential Plaza, Suite 4900, 180 North Stetson Avenue,

Chicago, Illinois 60601-6731

arf@leydig.com

wmueller@leydig.com.

ORBIT IP, LLP

Dated: April 23, 2025

By: /Marc Karish/
Marc Karish, Reg. No. 44,816
Bruce Chapman, Reg. No. 33,846
Attorneys for Watson Guide IP, LLC