STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

August 25, 2010

IN THE MATTER OF:

An Application for a Certificate of Need filed pursuant to Section 19a-639, C.G.S. by:	Notice of Final Decision Office of Health Care Access Docket Number: 09-31465-CON
Peter A. Gardell, DDS, P.C.	**Acquisition of a Cone Beam CT Scanner in Stamford**

To: Peter A. Gardell, DDS
Owner
Peter A. Gardell, DDS, P.C.
999 Summer Street
Suite 106
Stamford, CT 06905

Dear Dr. Gardell:

In accordance with the Connecticut General Statutes Section 4-179, the Proposed Final Decision dated August 18, 2010 by Hearing Officer Melanie A. Dillon is hereby adopted as the final decision of the Deputy Commissioner of the Office of Health Care Access, Department of Public Health in this matter. A copy of the Proposed Final Decision is attached hereto and incorporated herein.

Sincerely,

Kimberly R. Martone,
Director of Operations

KRM: cgc

cc: Melanie A. Dillon, Hearing Officer, OHCA/DPH

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

In Re: **Peter A. Gardell, DDS, P.C.**
Docket No. 09-31465-CON

FINAL DECISION

On August 18, 2010 a Proposed Final Decision was issued in the above matter pursuant to Section 4-179 of the Connecticut General Statutes. On August 24, 2010, Peter A. Gardell, DDS, P.C. waived the right to file exceptions and to present briefs and oral argument.

In accordance with Connecticut General Statutes Section 4-179, the attached Proposed Final Decision dated August 18, 2010 by Hearing Officer Melanie A. Dillon is hereby adopted as the final decision of the Deputy Commissioner of the Department of Public Health in this matter. A copy of the Proposed Final Decision is attached hereto and incorporated herein.

WHEREFORE, it is the final decision of the Deputy Commissioner that the application of Peter A. Gardell, DDS, and P.C. for the acquisition of a Cone Beam Computed Tomography Scanner is hereby approved.

8.25.10
Date

Norma D. Gyle, R.N., Ph.D.
Deputy Commissioner

Department of Public Health
Office of Health Care Access
Certificate of Need Application

Proposed Final Decision

Applicant: **Peter A. Gardell, DDS, PC**

Docket Number: **09-31465-CON**

Project Title: **Acquisition of a Cone Beam Computed Tomography Scanner**

Project Description: Peter A. Gardell, DDS, PC ("Applicant") is proposing to acquire a Cone Beam Computerized Tomography ("CBCT") Scanner in Stamford, at a total capital cost of $198,433.

Nature of Proceedings: On May 17, 2010, the Office of Health Care Access ("OHCA") received the Certificate of Need ("CON") application for the above-referenced project.

A notice to the public regarding OHCA's receipt of the Applicant's Letter of Intent to file its CON Application was published in *The Stamford Advocate* on October 9, 2009. OHCA received no responses from the public concerning the Applicant's proposal. Pursuant to Section 19a-639, C.G.S., three individuals, or an individual representing an entity with five or more people, had until June 7, 2010, the twenty-first calendar day following the filing of the Applicant's CON application, to request that OHCA hold a public hearing on the Applicant's proposal. OHCA received no hearing requests from the public.

A public hearing regarding the CON application was held on August 11, 2010. On July 22, 2010, the Applicant was notified of the date, time, and place of the hearing. On July 25, 2010, a notice to the public announcing the hearing was published in *The Stamford Advocate.* On July 28, 2010, OHCA granted a 15 day extension request by the Applicant to extend the final decision review period from the default date on August 15, 2010 to August 30, 2010. On August 3, 2010, Staff Attorney Melanie Dillon was appointed by Commissioner J. Robert Galvin to be the Hearing Officer and to rule on all motions, and to recommend findings of fact and conclusions of law. The hearing was conducted as a contested case in accordance with the provisions of the Uniform Administrative Procedure Act (Chapter 54 of the Connecticut General Statutes) and Section 19a-639, C.G.S.

The Hearing Officer heard testimony from the Applicant and in rendering this proposed final decision, considered the entire record of the proceeding. OHCA's authority to review and approve, modify or deny this proposal is established by Section 19a-639, C.G.S. The provisions of this section as well as the principles and guidelines set forth in Section 19a-637, C.G.S., were fully considered by OHCA in its review.

Findings of Fact

1. The Applicant is a dental practice located at 999 Summer Street, Suite 106 in Stamford. *(January 19, Initial CON Application, page 1)*

2. The Applicant specializes in general dentistry and is licensed by the State of Connecticut. *(January 19,2010, Initial CON Application, pages 25- 26)*

3. The proposed CBCT scanner will be installed in the Applicant's current location. *(January 19, 2010, Initial CON Application, page 9, and March 25, 2010, Completeness Responses, page 43)*

4. The current imaging equipment used for diagnosis includes a digital intraoral sensor and film based Gendex Panelipse X-Ray unit, which utilizes two-dimensional (2D) radiographs. *(January 19,2010, Initial CON Application, page 6)*

5. The Applicant will not dispose of the 2-D unit after the implementation of this proposal since not all patients will require the scan to be converted to the high definition 3-D rendering. *(March 25, 2010, Completeness Responses, Financial Attachment II, page 50)*

6. The target population is the Applicant's patients that currently have the following conditions: Edentulous (complete and partial), Periodontal disease, and Dental anatomy abnormalities (including wisdom tooth location and angulations). Some of these conditions are not known to the patient and cannot be seen with the Applicant's current imaging equipment. *(September 24, 2009, Letter of Intent, page 9)*

7. The Applicant testified that he will also provide CBCT scans to his implant placement patient population. *(August 11, 2010, Public Hearing Testimony of Dr. Peter A. Gardell)*

8. The Applicant refers out the most complicated implant cases and he will continue referring the more complicated cases to specialists; however, following the acquisition of the CBCT scanner, he will include the CBCT scan so the specialist will be able to provide better care to his patients. *(August 11, 2010, Public Hearing Testimony of Dr. Peter A. Gardell)*

9. The acquisition of the proposed CBCT scanner will increase the ability to diagnose oral pathology and provide superior service to the Applicant's patient population in a cost effective manner. *(January 19, 2010, Initial CON Application, page 6)*

10. The images taken with Panelipse film are of very high quality with minimal distortion evident on the film; however, due to the fact that it is a film based radiograph, the information contained cannot be manipulated for increased diagnostic value. *(January 19,2010, Initial CON Application, page 7)*

11. The CBCT scanner allows for a wide variety of adjustments to the data, decreasing the need for possible retakes. *(January 19,2010, Initial CON Application, page 8)*

12. The Applicant provided literature to support his testimony that the integration of his current technology, CEREC[1], and the proposed CBCT will allow him to perform precision implant placement planning that will reduce the treatment time by one third, thereby reducing the patient's cost, discomfort and radiation exposure. *(August 11, 2010, Public Hearing Testimony of Dr. Peter A. Gardell)*

13. Clearer images of higher diagnostic value are produced with the CBCT scanner versus traditional CT scanners because CT scans are surface rendered, which means they are susceptible to scatter created from dental restorations. The CBCT scanner is not affected to the same degree since the image is volume rendered. *(January 19, 2010, Initial CON Application, page 7, and August 11, 2010, Public Hearing Testimony of Dr. Peter A. Gardell)*

14. Since images produced by the CBCT scanner are volume rendered, it allows for detection of a fractured tooth prior to performing a root canal, which saves the patient time and money. *(August 11, 2010, Public Hearing Testimony of Dr. Peter A. Gardell)*

15. The Applicant does not refer patients out for traditional CT scans because it generates an additional expense for the patient, and if necessary, a specialist would make the determination as to whether or not a traditional CT scan should be performed. *(May 17, 2010, 3rd Completeness Responses, page 71)*

16. CBCT technology will allow the Applicant's practice to provide superior quality of service to its patients in a cost effective manner. For example, a scan on a traditional medical CT scanner in the Stamford area can range between $1,100 and $1,300 and is usually not covered by insurance. *(August 11, 2010, Public Hearing Testimony of Dr. Peter A. Gardell)*

17. The cost of a dental scan on a traditional CT scanner may deter some patients from following through with the treatment. *(August 11, 2010, Public Hearing Testimony of Dr. Peter A. Gardell)*

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[1] CEREC is a technology that can be used for a full range of single-unit indications: inlays, onlays, partial crowns, posterior crowns, anterior crowns and veneers; Article provided by the Applicant titled: "Integrating three-dimensional digital technologies for comprehensive implant dentistry", by Neal Patel,DDS, indicates that clinical research provides documentation of the success of ceramic restorations created using the CEREC system and that the integration of the proposed CBCT with the CEREC system called Galileos CEREC integration (GCI) software will provide the dentist with information to plan implant placement during the diagnostic and planning phases of the treatment.

18. The fees associated with the proposal are:

Table 1: Fee by Scanner Type with the Proposal

Scanner type	FY 2010	FY 2011	FY 2012	FY 2013
2-D	$175	$185	$195	$205
Cone Beam (3-D)	$500	$525	$550	$575

(January 19, 2010, Initial CON Application, page 40 and Financial Attachment II, pages 38-39 and Completeness Responses, pages 46-49)

19. The fees for the 3-D rendering are based on the current usual and customary fees accepted by insurance companies for the Applicant's zip code. (*March 25, 2010, Completeness Responses, page 54)*

20. A CBCT scanner compared to a traditional CT scanner provides a lower radiation dose to patients. An article provided by the Applicant indicates that a comparison with patient doses reported for maxillofacial imaging by traditional CT indicates that CBCT provides substantial radiation dose reductions of between 98.5% and 76.2%. *(August 11, 2010, Public Hearing Testimony of Dr. Peter A. Gardell, and Article by Scarfe WC, Farman AG., "What is cone-beam CT and how does it work?", Dent Clin North Am.2008 Oct;52(4):707-30)*

21. The Applicant also provided literature to support that his patients and each of the following disciplines of dentistry will benefit through a decreased number of surgeries, less post-operative discomfort and decreased cost from the detailed imaging provided by the CBCT scanner:

Table 2: CBCT benefits to patients and dentist by discipline of dentistry

Discipline	Benefits
Oral Surgery	3-D imaging will allow the practitioner to get an accurate view of the surgical site. Any deviation in normal anatomy will be known before the procedure is started and planned for, decreasing the complications of the surgery, the number of surgeries and the cost to the patient.
Implantology	With the pairing of the cone beam technology with the current CadCam technology, precision planning and execution of implant surgery is possible. It will minimize the complications of surgery; additional unplanned surgeries and the post operative discomfort the patients' experienced.
Periodontics	Better evaluation of topography of the bone, the quality of the bone and the associated anatomy of the surgical site prior to the commencement of the surgical procedure. Harvest sites for bone graft procedures can be evaluated for quality of bone.
Endodontics	The complex root canal system can be evaluated prior to commencement of the endodontic procedure. Conditions that can be picked up prior to retreatment include missed canal, inadequate fill, root fracture (horizontal and vertical), and perforation of furcation. Knowing these will save the patient from undergoing unnecessary treatment and incurring unnecessary costs.
Tempromandibular Joint Treatment	The ability to evaluate health of the condyle, disk and associated ligaments, eminence and joint capsule will help with the evaluation of the joint. Knowing the status of the tissues will allow for more targeted treatment with minimal invasiveness. Proper evaluation can avoid unneeded surgeries saving the patient discomfort and cost.

(January 19, 2010, Initial CON Application, pages 6-7)

22. The proposed CBCT scanner will allow the Applicant to provide his patients with superior diagnostic care and implant placements in a more efficient manner at a lower cost and a lower radiation dose to his patients than a traditional CT scan.

23. The Applicant provided the following historical utilization for procedures where the CBCT scanner may have been utilized:

Table 3: Applicant's Historical Utilization for Procedures Where CBCT May Be Utilized

	FY 2006	FY 2007	FY 2008	FY 2009*	Annualized** FY 2010	Overall Growth between FY 2006-FY 2009
Total	**151**	**201**	**270**	**265**	**361**	**75%**

Note: The Fiscal year is from January 1st to December 31st.
**The slight decrease in 2009 was attributable to removal of one practitioner's numbers as a result of utilization of different software by that practitioner*
***The Applicant contends that the 2010 volume was estimated based on the last quarter of 2009 because the new office was not functional until January 26, 2010 and patient treatment was not possible.*
(May 17, 2010, 3rd Completeness Responses, page 72)

24. Between FYs 2006 and 2009 the Applicant experienced a 75% overall growth of procedures where a CBCT scan may have been utilized.

25. The Applicant predicts an increase in volume with the proposal due to future increases in staff (hygienists), which will allow Dr. Gardell to perform additional procedures, and the typical increases following the relocation and renovation of a dental office. *(January 19, 2010, Initial CON Application, page 10, and March 25, 2010,Completeness Responses, page 45)*

26. The Applicant was unable to accept new patients at his former office due to a lack of capacity and he anticipates an increase in the number of patients at his new office due to increased capacity. *(March 25, 2010,Completeness Responses, page 45)*

27. The following table represents the Applicant's projection with respect to the number of procedures where a CBCT scan may be utilized:

Table 4: Projected Number of Procedures Where CBCT Scan May Be Utilized

	FY 2011	FY 2012	FY 2013	Average FY 2011-2013
Total Number of Procedures	**462**	**553**	**649**	**554**

Note: The Fiscal year is from January 1st to December 31st.
(January 19, 2010, Initial CON Application, page 10, March 25, 2010, Completeness Responses, pages 43-44, and April 15, 2010, 2nd Completeness Responses, page 65-67, and May 17, 2010, 3rd Completeness Responses, page 73, and Financial Attachment II, pages 76-79)

28. The number of procedures as reflected in Table 4 does not equal the number of CBCT scans, as one CBCT scan may be utilized for multiple procedures. *(May 17, 2010, 3rd Completeness Responses, page 73)*

29. Based upon the volume projections with respect to procedures that may require a CBCT scan, the Applicant projected the number of CBCT scans as follows:

Table 5: Projected Number of CBCT Scans

	FY 2011	FY 2012	FY 2013	Average FY 2011-2013
# of CBCT Scans	**60**	**65**	**65**	**63**

Note: The Fiscal year is from January 1st to December 31st.
(January 19, 2010, Initial CON Application, page 10, March 25, 2010, Completeness Responses, pages 43-44, and April 15, 2010, 2nd Completeness Responses, page 65-67, and May 17, 2010, 3rd Completeness Responses, page 73, and Financial Attachment II, pages 76-79)

30. The majority of the Applicant's patient volume comes from Stamford. *(January 19, 2010, Initial CON Application, page 10)*

31. The Applicant performed five implant placements between January 1 and August 9, 2010 and once the CBCT is in place he will be able to increase the number of implant placements at his office since he currently has fifteen patients waiting for this new technology to be implemented. *(August 11, 2010, Public Hearing Testimony of Dr. Peter A. Gardell and Exhibit I)*

32. OHCA finds that volume projections are reasonable and achievable based upon the Applicant's historical utilization with respect to procedures where a CBCT scan may be required.

33. The proposed total capital expenditure for this proposal includes the lease of the equipment, and costs associated with the non-medical equipment purchase, construction/renovation and capitalizing financing costs:

Table 6: Proposal's Total Capital Expenditure

Equipment Lease	$150,000
Non-Medical Equipment Purchase	10,000
Construction/Renovation	3,000
Capitalizing Financing Costs	35,433
Total Capital Expenditure	**$198,433**

(January 19, 2010, Initial CON Application, page 34)

34. The lease for the CBCT will be through Patterson Dental for a period of 60 months. *(March 25, 2010, Completeness Responses, page 45)*

35. The Applicant projects the following gains from net income for the overall practice for the first three projected years of the proposal of $261,180, $295,900 and $325,350, for FYs 2011, 2012 and 2013, respectively. *(May 17, 2010, 3rd Completeness Responses, page 75, Financial Attachment I)*

36. The Applicant's incremental gains with the proposal indicate a consistent increase in income from operations:

Table 7: Incremental Gains to the Project

Description	FY 2011	FY 2012	FY 2013	Total
Incremental Revenue from Operations	$50,060	$60,580	$63,410	$174,050
Incremental Total Operating Expense	$30,880	$30,880	$30,880	$92,640
Incremental Gains from Operations	**$19,180**	**$29,700**	**$32,530**	**$81,410**

(May 17, 2010, 3rd Completeness Responses, Financial Attachment I, page 75)

37. There are no losses associated with this proposal. (*January 19, 2010, Initial CON Application, page 40)*

38. OHCA finds that the Applicant's proposal is financially feasible based upon the Applicant's projections with respect to incremental and overall gains for the practice.

39. The Applicant testified that based on information and experience of some of his colleagues out of state who currently own a CBCT the following companies would reimburse for certain procedures: Metlife, Delta Dental, Aetna, Cigna, and Guardian. *(January 19, 2010, Initial CON Application, page 40, and August 11, 2010, Public Hearing Testimony of Dr. Peter A. Gardell)*

40. The procedure codes for CBCT procedure include CDT code D.0360 for Cone Beam Capture, D0362 2D for the reconstruction of cone beam capture and D0363 for 3-D reconstruction of cone beam capture. *(January 19, 2010, Initial CON Application, page 40)*

41. The current and projected payer mix for the Applicant's total practice based on patient population is as follows:

Table 8: Total Practice Current & Three-Year Projected Payer Mix

	FY 2009 Current	FY 2010 Year 1	FY 2011 Year 2	FY 2012 Year 3
Medicare*	0%	0%	0%	0%
Medicaid*	0%	0%	0%	0%
Champus and TriCare	0%	0%	0%	0%
Total Government	**0%**	**0%**	**0%**	**0%**
Commercial Insurers*	60.0%	60.0%	60.0%	60.0%
Uninsured/Private Pay	39.9%	39.9%	39.9%	39.9%
Workers Compensation	0.1%	0.1%	0.1%	0.1%
Total Non-Government	**100%**	**100%**	**100%**	**100%**
Total Payer Mix	**100%**	**100%**	**100%**	**100%**

** Includes managed care activity;*
(January 19, 2010, Initial CON Application, page 37)

42. The 60% for commercial insurers is based on the success rate of some of his colleagues in other states that have submitted claims to insurers and received payment for the procedure codes related to the CBCT scanner as referenced in Finding 40. *(August 11, 2010, Public Hearing Testimony of Dr. Peter A. Gardell)*

43. A change in the payer mix is not anticipated; therefore, the payer mix for the CBCT scanner will reflect the same numbers as those for the total practice payer mix. *(May 17, 2010, 3rd Completeness Responses, page 74)*

44. The Applicant provided literature demonstrating that the proposal is consistent with its long-range plans to provide its patients with the most efficient dental services and updated technology available. *(January 19, 2010, Initial CON Application, pages 40 and 17-24)*

45. The Applicant is a faculty member at the Scottsdale Center for Dentistry. *(August 11, 2010, Public Hearing Testimony of Dr. Peter A. Gardell)*

46. The Scottsdale Center is implementing a formal curriculum regarding CBCT technology and the CBCT scanner will allow the Applicant to further his research in this field and expand his teaching possibilities. *(August 4, 2010, Prefiled Testimony of Dr. Peter A. Gardell, page 81)*

47. The Applicant testified that the CBCT technology is still in its infancy and there are many opportunities for research, especially integrating it with CEREC® technology. *(August 11, 2010, Public Hearing Testimony of Dr. Peter A. Gardell)*

48. The Applicant also testified that there are opportunities for performing studies that involve Oral Maxillofacial Facial Radiologists. These studies focus in the area of continual education in oral pathology. *(August 11, 2010, Public Hearing Testimony of Dr. Peter A. Gardell)*

49. The Applicant is currently a local trainer in the CEREC® technology and hopes to do the same for the CBCT technology. *(August 11, 2010, Public Hearing Testimony of Dr. Peter A. Gardell)*

50. The CBCT scanner will allow the Applicant to further develop his research and writing responsibilities with respect to the integration of CEREC and CBCT technology.

51. The Applicant has demonstrated that he has sufficient technical and managerial competence to provide efficient and adequate services to the public.

Rationale

OHCA approaches community and regional need for CON proposals on a case by case basis. CON applications do not lend themselves to general applicability due to a variety of factors, which may affect any given proposal; e.g., the characteristics of the population to be served, the nature of the existing services, the specific types of services proposed to be offered, the current utilization of services and the financial feasibility of the proposal.

The Applicant specializes in general dentistry with his dental practice located in Stamford, Connecticut. The Applicant's current imaging equipment includes a digital intraoral sensor and a film based Gendex Panapelise X-Ray unit, which utilizes two-dimensional (2D) radiographs. The Applicant proposes to acquire a CBCT scanner, providing him with the ability to scan patients with Edentulous (complete and partial), Periodontal disease, and Dental anatomy abnormalities. The Applicant also intends to utilize the CBCT scanner for his implant patients [Findings 6 & 7].

The proposed CBCT scanner will increase the Applicant's ability to diagnose oral pathology and provide superior diagnostic care to the target population in a cost effective manner [Finding 9]. It will also allow for a wide variety of adjustments to the data, thereby, decreasing the need for possible retakes [Finding 11]. The Applicant will be able to perform precision implant placement planning that will reduce the overall treatment time [Finding12]. Additionally, the proposed CBCT scanner produces images of higher diagnostic value at a lower cost and lower radiation dose than those produced with the traditional CT scanners [Finding 22]. Accordingly, OHCA finds that the proposal will positively impact the quality, accessibility and cost effectiveness of health care provided to the Applicant's patients and to the residents of the Stamford area.

The Applicant anticipates an increase in volume with respect to the proposal due to an increase in staff and the relocation and renovation of his office, as the Applicant will have more time to perform additional procedures and increased capacity to accept new patients [Findings 25-26]. The Applicant also anticipates an increase in the number of implants that he is able to perform as he currently has fifteen additional patients waiting for him to acquire the CBCT scanner [Findings 30]. OHCA finds that volume provided by the Applicant appears to be reasonable based upon the historical utilization for procedures where a CBCT scan may have been utilized and anticipated increases in the implant patient volume.

The total capital cost associated with this proposal is $198,433. The Applicant plans to lease the proposed CBCT scanner from Patterson Dental for a period of 60 months [Findings 29& 30]. The Applicant projects the following gains from net income for the overall Practice for the first three projected years of the proposal of $261,180, $295,900 and $325,350, for FYs 2011, 2012 and 2013, respectively [Finding 31]. The projected fees associated with the CBCT proposal are: $500, $525, $550, and $575 for FYs 2010, 2011, 2012 and 2013, respectively [Finding 18]. Based on rates and projected gains OHCA finds that the proposal is financially feasible [Finding 33].

Order

Based upon on the foregoing Findings and Rationale, the CON application of the Applicant to acquire a dental CBCT scanner in Stamford, Connecticut, with an associated capital cost of $198,433 is hereby **GRANTED.**

Based upon the foregoing, I respectfully recommend that the Deputy Commissioner approve the application of Peter A. Gardell, DDS, P.C. to acquire a CBCT scanner in Stamford, Connecticut, with an associated capital cost of $198,433

8-18-10
Date

Melanie A. Dillon, Esq.
Hearing Officer

MAD:cgc

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TO: DR. PETER A. GARDELL

FAX: (203) 363-0080

AGENCY: PETER A. GARDELL, D.D.S., P.C.

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Comments:
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